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# An investigation into the information-seeking behaviour of professionals, working within the pharmaceutical manufacturing sector in Ireland.

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### Introduction

The Irish pharmaceutical production sector is a highly regulated environment, where both manufacturing and distribution are subject to European, U.S. and other international regulations, directives and guidance documents. These include, for example, 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2017' published by the Medicine and Healthcare Regulatory Agency in the U.K., which is known in the industry as the 'Orange Guide' (MHRA, 2017); the Irish Health Product Regulatory Authority (HPRA, 2014) and the US 21 Federal Code of Regulation Parts 210 & 211 and Guidance documents (FDA 2017). In addition, pharmaceutical production work is conducted within an information rich environment, where strategic goals of quality products, creativity, continuous improvement, greater efficiencies, and a drive for "right the first time (RFT) without a time delay" (Torkka et al 2014 p. 175) are of paramount importance. For example, Bawden & Robinson (2011, p. 65) discuss how pharmaceutical information "is required and produced at all stages of the development and use of medicines, from the earliest stages of the multi-disciplinary R. D. team, through clinical trials and regulatory approval" (Bawden & Robinson 2011 p. 65). Within a manufacturing context, pharmaceutical information can include (but is not limited to) multijurisdictional regulations and international standards & guidelines, corporate and in-house procedures & guidelines, manufacturing plant commissioning/qualification documentations, production records, and documentation pertaining to quality/compliance/regulatory support services. In addition to handling vast amounts of information, those working within the pharmaceutical production sector are operating within a high-performance working environment, where efficient use of time is imperative (Torkko, et al., 2014) and where enhanced information seeking abilities and information systems are beneficial (Bawden & Robinson, 2011, p. 24).

During the global COVID-19 pandemic, which the World Health Organization described as an 'infodemic', a phenomenon, where false and misleading information can result "to mistrust in health authorities and undermines the public health response" (2022), the importance of regulatory processes of pharmaceutical products was further intensified. A number of studies also stressed the accessibility of community pharmacists (Baratta, Ciccolella and Brusa, 2021, p.18) and as an extension their "responsibility in providing accurate patient education and health information" (Al-Daghastani et al. 2021, p.10). During the pandemic pharmacies around the world remained open and were the "accessible healthcare service and many people's first point of contact with the NHS." (All-Party Pharmacy Group). At the same time the need for urgency around the pharmaceutical production requirements surrounding the vaccination process, i.e., clinical trials, production and approval processes, meant a need for "simplification and removal of disproportionate or non-risk-based barriers administrative barriers" (OECD, 2020) for ensuring a fast response around regulatory and compliance issues, as urgency was critical. In that fast changing and unpredictable environment, a rapid response was made possible on the basis of an established and effective regulatory system, a knowledge base with networks and information sharing processes that were already in place. In other words, a pre-existing well-practiced and highly regulated working environment allowed the fast process and use of good quality and accurate information to cascade to others.

Although the pharmaceutical production environment presents a complex and information-rich working context, a paucity of research exists with respect to the information seeking behaviour of professionals

working within the pharmaceutical manufacturing sector. Previous research has examined the nature of information that is required by R&D scientists engaged in drug discovery and clinical trials (Cole & Bawden, 1996), the effects of knowledge sharing on improved innovative performance (Lilleoere & Hansen, 2011) and organisational creativity (Sundgren, *et al.*, 2005, p. 360) or the lack of it /resistance to it between professionals (Athar Mahmood & Evans 2015; Lilleoere & Hansen, 2011). Yet, more empirical research is required on the basis of the information seeking behaviour of professional groups working within the pharmaceutical production sector, engaged in process technology or process development, regulatory support, quality/compliance support and engineering roles.

The context of this research, Ireland, is a leading location for pharmaceutical manufacture, generating in excess of 50 percent of the country's exports, and making Ireland the "largest net exporter of medicines in the EU" (Irish Pharmaceutical Healthcare Association 2019). The industry directly employs over 25,000 people, with an equivalent number employed in support services to the sector. 65% of individuals employed in the sector are third level graduates. Approximately 120 overseas companies have plants in Ireland, including 9 of the 10 largest pharmaceutical companies in the world. Relatively new to Ireland (1960s), the industry has progressed from being mainly a location for bulk manufacture of active pharmaceutical ingredients for export, to that of a producer of finished products (parenteral, tablets, capsules, ophthalmic preparations, topical treatments etc.), with a number of companies pursuing research & development, and establishing research links to Irish universities. Through this progression, the pharmaceutical industry in Ireland has developed to include traditional pharmaceuticals, biopharmaceuticals and medical devices (Irish Pharmaceutical Healthcare Association, 2019; IDA Ireland, 2019).

The aim of this research focused on investigating the Information Seeking Behaviour (ISB) and information needs of different professional groups within the pharmaceutical manufacturing sector in the Republic of Ireland (i.e. for what purpose information is acquired), the information sources they use (including in-house documentation, regulations, industry guidelines, standards, colleagues) and the factors, which influence their choice of information sources.

Furthermore, the research explored the perceived level of support that exists towards knowledge & information sharing as an important aspect of ISB within an organizational environment. The concept of information sharing or 'information transmission' and its key positioning in ISB research has been previously extensively reviewed by Savolainen (2017), who has conceptualized it as "communicative activities" within the framework of ISB and with reference to empirical studies that have explored types of information sharing (Almehmadi, Hepworth and Maynard, 2004), sharing practices (Pilerot, 2014) as well as diverse methods for disseminating information to others within different information intensive working environments (e.g. design researchers, patent engineers, academics). Talja (2006) has defined information sharing as sharing of "already acquired information, incorporating both active and explicit and less goal oriented and implicit information exchanges" (p.114). Du (2014) has similarly described it as being the explicit and implicit information exchanges between people, groups, organisations, and technologies. For information sharing to occur within an organisation, an supportive environment (e.g. person-to-person sharing & collaborative sharing) through the accommodation of sharing enablers, must exist. This study therefore explored both explicit and tacit levels of knowledge with a specific interest on the diversity of knowledge sharing enablers, i.e. reliable internet access, access to online information sources, training available on information resources, intranet site navigability, adequate time for sharing information, organisational structure that facilitates a sharing culture, and the availability of subject matter experts.

# **Theoretical framework**

The General Model for Information Seeking Professionals (GMISP), developed by Leckie *et al.*, (1996), was used as a framework to examine the ISB of professionals within the pharmaceutical manufacturing sector, focusing on the task driven nature of information needs within a manufacturing environment. The GMISP model theorises that information needs arise out of situations pertaining to specific tasks, associated with work roles, arguing that the conceptualisation of why and how a professional seeks information cannot be reduced to a simplistic analysis of sources alone. Therefore, greater understanding is required of the various roles a professional performs and the associated tasks that prompt a need for information (Leckie *et al.*, 1996, p. 187). The model addresses the following constructs: work roles, associated tasks and the characteristics of information needs.

A recent conceptual analysis by Savolainen (2017) similarly places emphasis on the information needs construct "as a root factor which motivates people to identify and access information sources", describing it also as "a trigger providing an initial impetus to information seeking". However, "a secondary trigger or driver" is also in operation that is "determined by more fundamental factors, for example, the information requirements of task performance" (2017, p. 2). Furthermore, there are many facets associated with an information need. The circumstances under which an information need arises can vary greatly, for example, from an unexpected information need connected to a low urgency task and low complexity, to one of great urgency and high complexity. As Savolainen, explains, "The level of complexity, the degree of importance and urgency, and whether the information need is anticipated or unexpected together will affect when and how strong an information need will trigger the information-seeking activity" (Savolainen, 2017, p. 14). This idea becomes even more complex as professionals assume "a multiplicity of roles in the course of their daily work" (Leckie *et al.*, 1996, p. 181). Overall, information needs are determined by a number of variables or factors influencing the nature of the professionals' information needs, including:

- Individual demographics (age, specialty, career stage)
- Context (Specific need, internally or externally prompted)
- Frequency (recurring or new)
- Complexity (degree of)
- Importance (urgency of)
- Predictability (anticipated or unexpected) (Leckie *et al.*, p.183).

#### Work Roles and Tasks within the Pharmaceutical sector

Previous research by Du (2014) has found that information needs generated from work tasks are specific in nature, and indicate varying requirements. In order to gain an insight into information seeking behaviours of pharmaceutical professionals, it is essential to develop an understanding of the different types of tasks undertaken specifically by those in roles which involve process technology / process development, engineering, regulatory support and quality / compliance support. Associated tasks that can be included within the different roles are summarised below.

# {Please place Table 1 about here}

A pharmaceutical professional employed in a *Regulatory Support* role may be tasked with seeking and sourcing information from a variety of sources, both formal and informal, internal & external, oral & written, as well as their own personal past experience and knowledge gained, as posited by Leckie et al (1996). The preparation of

global regulatory submission documentation, or the preparation & compilation of marketing authorisation documentation (Kumar, Panwar & Singh, 2013 and Gummerus *et al.*, 2016) may trigger information retrieval from multiple avenues: change control documentation (electronic, written and paper text sources), regulatory information in relation to that particular jurisdiction for submission, previous submissions examples, industry publications, other colleagues and consultants, and external sources such as conference proceedings and information on industry trends. There may also be a supervisory or training role to address.

The role of a pharmaceutical professional engaged in *Quality/Compliance* support activities can vary greatly, where some individuals are involved in procedural compliance and auditing tasks, whereas others are engaged in direct production support activities from batch record issuance, review and control, or raw material release activities for batch production to product testing. *Engineers* working in the pharmaceutical sector typically work as part of a team and require information to support day to day operations for a production facility, or for the execution, commissioning, and validation of equipment & building upgrade projects, and new-build projects. For those in a project team concerned with the start-up of a new production facility, their role may require performing multiple tasks: new equipment & system design specifications, their installation, calibration, commissioning and validation. At the various stages of the project, the information sources can range from design specifications, engineering drawings, to liaising with their colleagues in the field (project site) troubleshooting systems & equipment, to consultation with the project client i.e. the Production or Quality Departments.

*Engineers* involved in project work will draw on live data (instrument readings) and observation, coupled with their own experience and knowledge, and that of their co-workers as sources of information. In information seeking "oral communication is predominant, just as is the reliance on co-workers and supervisors' knowledge", with engineers relying on "personal file, personal knowledge and personal experience" (Leckie *et al.*, 1996, p. 165). For those supporting day to day operations within a live production facility, their work-related tasks are centred around preventative maintenance and breakdown support on existing equipment. Thus, a need for up-to-date accurate information is a key requirement to facilitate them in planning and completing their work.

Pharmaceutical professionals engaged in *Process Technology / Process Development* roles, typically work as part of a team in conjunction with personnel from the Quality and Production Departments, with a focus on the optimisation of plant operations and systems.

A process development specialist involved in a product transfer to site will be required to liaise with the product owner to ensure all product technical knowledge, learnings and best practices have been captured and embedded, to facilitate performance improvement and systems of working (McKenzie *et al.*, 2006). Such a project will involve multiple tasks, each triggering multiple information needs, with subsequent information seeking from a variety of sources including people, information systems, technical documents, and regulations.

#### Information awareness, information sources and information outcomes

In addition, to the central positioning of professional roles and the performance of work-related tasks, the GMISP model emphasizes three particular factors affecting information seeking: a) information awareness, b) information sources and c) information outcomes.

#### a) Information Awareness

Leckie et al., (1996) discuss a number of awareness factors influencing information utilization by professionals,

determining the effort a professional will spend in seeking information from a given source: **source familiarity**, **prior success** with a particular source, **trustworthiness cost**, **and time and effort**. In addition, **effort** can be both **psychological**, e.g. learning a new information source, or **physical**, e.g. with information archived off site and can only be viewed in situ (pp. 185-86).

#### {Please place Table 2 about here}

#### b) Information Sources

Information sources can be **formal** or **informal** sources, **internal** or **external**, **written**, **oral** or **personal sources**. Knowledge and perception of the various information sources as well as their accessibility (on the basis of its physical proximity and language) are factors influencing professional information seeking behaviour. In addition, the quality of the source and the packaging of information, via a specific medium, impacts on its convenience and usefulness (Leckie *et al.*, 1996, pp. 184-85). Quality attributes include the accuracy of the information, the specificity of the source in relation to the problem being addressed, and its relevance and reliability (Li Lu & Yuan, 2011). From a pharmaceutical sector and more contemporary perspective, accessibility may also involve whether a professional has access rights to information held on electronic databases and electronic reference texts as well as whether electronic information is a suitable format file and readable to the user; the professional will need to have the necessary software to open an information file.

#### {Please place Table 3 about here}

#### c) Information Outcomes

Information outcomes are an important component of professional information seeking with associated feedback loops. In response to a work role associated task, an information need is a trigger, which results in the initiation of an information seeking process, with "the optimal outcome is that the information need is met and the professional accomplishes the task at hand, such as completing a technical report" (Leckie *et al.*, 1996 p. 187). For professionals working within the pharmaceutical manufacturing sector such outcomes can include procedure preparation and approval, completion of an equipment design specification or a regulatory change authorisation report, completion of a license check inquiry, closeout of an audit observation, as well as numerous technical reports. In the event that the information seeking process has not been successful, further information seeking is required, which is referred to as "feedback loop" and knowledge gained may also benefit another task or role (Leckie *et al.*, 1996, p. 187).

#### {Please place Table 4 about here}

Since its inception, the GMSP model has been tested in numerous studies with different professional groups. For example, Landry (2006) examined dentists and Kwasitsu (2003) studied engineers engaged in micro chip design and manufacture. However, the GMSP model has, so far, not been empirically tested involving professionals within the pharmaceutical sector.

#### **Knowledge & Information Sharing**

As organisations become more information-intensive, information is becoming more fragmented across

multiple actors, artifacts, and systems (Hansen & Järvelin, 2005). As a result, information sharing and collaboration, in practice, have become an important focus for organisational work (Du, 2014). Information exchange and knowledge sharing between employees within pharmaceutical R&D can also play a significant role in creating a "collective learning environment" with the purpose of finding innovative solutions and reducing costs as effort is not duplicated individually (Sundgren *et al.*, 2005, p. 361; Athar Mahmood & Evans, 2015, p.298). Therefore, the study of knowledge and information sharing within the pharmaceutical sector is equally important area to explore more empirically.

# **Data Collection and Analysis**

A quantitative non-experimental research design, comprising of a self-completion survey questionnaire was used in this research. The deployment of a self-completion questionnaire as a data collection instrument provided a means to collate "quantitative or numeric description of trends, attitudes, or opinions of a population by studying a sample of that population" (Creswell, 2009, p. 145), the aim of which was to "obtain information which can be analysed and patterns extracted and comparisons made" (Bell, 1999 p. 13), reducing bias, supporting anonymity of participants and facilitating respondent convenience. The target population for research were professionals working within the Pharmaceutical Manufacturing Sector in Ireland, encompassing both GLP (Good Laboratory Practice) and GMP (Good Manufacturing Practices) environments. Job titles within the Pharmaceutical Manufacturing Sector can vary from company to company; however, job function and responsibilities may be quite similar. Therefore, professionals engaged in the following job functions / responsibilities, or working role categories participated in the research:

- Process Technology / Process Development roles.
- Regulatory Support roles.
- Quality / Compliance Support roles.
- Engineering roles (including Commissioning, Qualification, Validation, Process and Automation activities)

#### Sampling Approach

A comprehensive listing of the population of interest was not available and, due to the already high workload of employees in this sector, initial attempts to engage companies directly were not successful, with only a single company replying to the call for participants. As a result, the study followed, a non-probability purposive snowball sampling approach, with a known network of contacts working within the sector as a starting point. The findings generated from this research process are, therefore, not representative of the general population of the target group or subgroups. Further limitations may also include differences in company size across the participants surveyed, or differences in the pharmaceutical raw materials across the participating companies, e.g., API (Active Pharmaceutical Ingredients) versus Biopharmaceuticals or Bulk Manufacturing. However, common to all companies (and employees) that took part in the study was that they were subject to operating within a highly regulated environment, as it is typical for the sector. Further study would be required to investigate what differences may exist across the subsectors, or how company size may impact on information behaviours for pharmaceutical professionals. However, these considerations were beyond the purposes of this study.

To improve validity and reliability of the collected data, and to produce a clear, unambiguous survey of appropriate length and format (and assist in increasing the response rate), a paper based draft questionnaire was prepared and piloted with two persons working within the industry; one person from a technical production support area and another one from human resources, to review at both a technical and a business

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appropriateness level. Following feedback from this initial pilot, the survey was refined, removing any ambiguities. At that point the survey was re-drafted using the online survey platform SurveyMonkey<sup>®</sup> and repiloted to a person from a technical / quality background, familiar with the target population and sector, but not working within the pharmaceutical sector. Feedback from this piloting was addressed and the survey was further refined, including enhancement of the survey visual presentation to facilitate ease of use for the participants.

An invitation (via email) to participate in the survey was forwarded to 84 individual contacts from the researchers list of associates, out of whom, 76 invitees accepted the invitation to partake. These individuals were also invited to identify and forward the survey link to further suitable participants. Communication requesting participation provided assurance that no personal identifying information, no company identifying information or no confidential business sensitive information would be requested as part of the survey and the confidential handling of all data acquired through the questionnaire and anonymity of those participating, was guaranteed.

A total of 90 survey responses were received over a 9-week period, running from December 2016 to January 2017. The survey questions addressed both demographic and target data. The first set of questions focused on the participant demographics: their gender, age group, number of years working within the sector, highest level of education achieved and subject area, identification of their working-role category, their level within the organisation and a description of company activities, with all questions answered by selection from a preprepared list of possible answers.

The elements of ISB examined included components of the GMISP model Leckie et al. (1996), including the following elements:

- Information Triggers examining the frequency of different information triggers (i.e. problem solving, production planning, process improvement, recurring task, unexpected task, decision making, high degree of urgency, high degree of complexity, document preparation, administration task and information request) while performing different work-related tasks (i.e. process Technology / Process Development, Quality / Compliance Support, Regulatory Support, Engineering).
- 2. Sources of Information exploring procedures, Health Authority Regulations HPRA, FDA and other such agencies, health & safety regulations, international standard, industry guidelines, in-house technical reports, technical reports produced by professional bodies, supplier technical reports, sector publications, scholarly journals, professionals associations, standards organisations, conference proceedings, in-house documentation, corporate intranet, internet, colleagues, technical experts, consultants, forum, meeting, working groups, seminars, internal & external sources, corporate networking communities, personal memory & personal files.
- 3. Factors of Influence for Choice of Information Source addressing prior success with particular source, familiarity of source, previously completed training on an information source, accessibility, knowledge of the various information sources, cost (time or effort), monetary cost, quality of the information, trustworthiness, information currency, its convenience & usefulness and personal contact to the source.
- 4. Information Enablers to Information Sharing examining reliable internet access, access to online information sources, intranet site navigation is user-friendly, adequate time to share information, organisational structure facilitates sharing, training in available information resources and the availability of subject matter experts. In additional, the study examined participants' perceived level of support available towards information sharing.

All questions were answered through a 5-point rating scale, allowing participants to express the frequency with which they encountered the item, or to articulate their level of agreement / disagreement. The survey was piloted with two persons working within the sector and with a person from a technical / quality background, familiar with the target population & sector, but not working within the pharmaceutical sector. Feedback from this piloting helped to produce a clear, unambiguous survey of appropriate length & format and to enhance its visual presentation.

#### Statistical Analysis

Statistical analysis was performed using SPSS software (version 24.0) and Excel, on collected data across the four sub-groups within the target population. Descriptive analysis was performed on all demographic data collected. Mean and standard deviation calculations were performed for each ISB item, with group means and overall means determined for each item. This was followed by comparative statistical analysis of all ordinal data collected across the four groups, i.e. data pertaining to information behaviour.

The non-probability sampling technique used (snowball sampling) generated non-parametric data. Nonparametric statistical methods of analysis are recommended for small sample sizes (where n < 30) and where the original populations are not normal; that is not representative of the population (Mendedhall, Beaver & Beaver p. 630). The sample sizes for 3 of the 4 interest groups can be considered small., with the 4<sup>th</sup> group n=37. The Kruskal-Wallis one-way analysis of variance by rank test (or H test) for non-parametric data, was used to compare the four groups for each target data item i.e. each information trigger, information source, information choice influencer and perceptions with respect to enablers to information sharing. The mean rank values for each target data item (the information behavior and enabler variables of interest) were utilised in the analysis. Applied across all four groups, the Kruskal-Wallis determined if a probable difference existed within the groups (P>0.05), by testing if the samples came from identical population distributions (Chan & Walmsley, 1997, p. 1755).

Further post-hoc testing was applied across all four group pairings, for each variable where differences were detected, using Mann Whitney U Test non-parametric data to determine where in the four groups the probable difference occurred. Previous empirical ISB studies have used the Mann Whitney U Test for comparing two groups (Kostagiolas *et al.*, 2013). A matrix approach was deployed to capture all possible group pairings.

# Results

A total of 88 participants were suitable for inclusion in the final results analysis, as two participants failed to identify which target population they were members of.

# Demographics

More than a third of respondents (34.1%, n=30) were female, and 65.9% (n=58) were male. Half of the survey population (50%, n=44) fell within the 45 to 54 age category and 90.9% (n=75) of participants were aged 35 years or more. The experience of respondents working within the sector ranged from 1 to 33 years, with an average work experience of 18.94 years, indicating an overall mature and experienced sample. Levels of education ranged from Certification to PhD. Of those surveyed, degree level was the most prevalent education level attained (39.8%, n=35), with the subject areas including the Engineering disciplines (Chemical, Process &

Mechanical), Analytical Science, Biosciences & Biotechnology, Chemistry, Microbiology, General Science, Pharmaceutical Science, Food Sciences & Technology and Architecture. Degree level attainment was followed by those having achieved to Masters Level, at 28.4% or 25 respondents. The subject areas within this cohort of professionals were Analytical Chemistry, Biotechnology, Pharmaceutical Technology, Pharmaceutical Analysis, Pharmacy, Engineering (Chemical, Biochemical, Biopharmaceutical, Pharmaceutical, Electronics) and Microbiology. 12 respondents (13.6%) attained Graduate Diplomas in various subjects including Engineering, Analytical, Chemistry, Microbiology and other science related areas. 10.2% of respondents (9 individuals) held PhDs in the science related domains of Biochemistry, Chemistry, Pharmacy, Microbiology and Physiology. 16 participants (out of 88) did not provide information regarding their subject area of study in their survey responses (Table 5). 

#### *{Please place Table 5 about here}*

The majority of the participants were engaged in engineering roles, followed by those in quality/compliance support roles, process technology development roles and finally regulatory support functions. As two out of the four groups had lower numbers of respondents a non-parametric data was used for cross-groups comparisons (Figure 1).

#### {*Please place Figure 1 about here*}

In relation to the working roles, 27.3% (n=24) described themselves as belonging to middle management, followed by contractors (25%, n=22), individual contributors (17%, n=15) and senior management (12.5%, n=11 participants). Individual contributors can be described as employees not having a department or group management function, but rather their function was as subject matter experts. This would also be applicable to those described as associates (3.4% of participants). Coordinators (4.5%, n=4 participants) work-role responsibilities focused on the overseeing, planning and the organisation of interdepartmental site goals (Figure 2).

#### *{Please place Figure 2 about here}*

Most of the participants (64.8%, n=57) were employed in larger production facilities (i.e. employing greater than 450 people), followed by those working in mid-sized production plants (18.2%, n=16) (Figure 3).

#### *{Please place Figure 3 about here}*

Of those surveyed almost half at 48% were employed with companies engaged in bio-pharmaceutical sector of the industry. 18% described their company's activities as finished product, 14% jointly as bulk pharmaceutical and pharmaceutical, and 6% of those surveyed participants described their companies' activities belonging to the medical device sector (Figure 4).

#### *{Please place Figure 4 about here}*

#### Information seeking behaviour

The survey collected data pertaining to the frequency of information triggers, demonstrated that different roles prompted specific work-related tasks with different frequency (mean frequencies were calculated within each group category on the basis of a 5-point Likert scale 1 'not frequently' to 5 'very frequently').

#### Information needs triggers and work role categories

In relation to information needs triggers related to *Process Technology/Process Development* roles the most frequently encountered prompts were *Problem Solving* (overall mean value=4.25) and *Decision Making* (overall mean value=4.13), followed by *High Degree of Urgency* (overall mean value=4.06), and *High Degree of Complexity* (overall mean value=4.00).

The results obtained in relation to *Quality/Compliance Support* roles indicated similar results with the most frequently encountered information triggers *Problem Solving, Decision Making, High Degree of Urgency* and *High degree of Complexity but with lower frequency of use* (mean values of 3.96, 3.96, 3.89 & 3.74 respectively).

*Regulatory Support* demonstrated that *High Degree of Urgency* was the mostly frequent information trigger (n=4.00), followed by *Document Preparation* (mean value=3.88) and then by *Degree of Complexity* and *Decision Making* (mean value in both categories=3.75).

*Engineering* most highly frequently mentioned triggers were *Decision-Making* (mean value=3.95), *High Degree of Urgency* (mean value=3.83) and *High degree of* Complexity and *Problem Solving* (overall mean value=3.62).

Less frequent information needs triggers were *Production Planning which reached its highest value in relation to Production Planning* (overall mean value=3.06) but achieved the lowest frequency results in the area of *Engineering* (overall mean value=1.89). Lower values were also observed in relation to *Administration* Tasks (Table 6).

#### Cross group comparisons

Kruskal-Wallis comparative statistical analysis was applied across the four pharmaceutical professional groups of *Engineering*, *Process Development/Technology*, *Compliance/Quality Support* and *Regulatory Support* and *Information Triggers*. The null hypothesis ( $H_o$ ) stipulated that there would be no difference amongst the four groups (where P > 0.05). On the basis of that analysis, only one significant difference was identified, *Production Planning* (P=0.008), suggesting that a difference existed for at least one of the different roles. Post Hoc testing indicated that differences were present between *Engineers* and *Process Development/Technology* roles (P=0.002), and between *Engineers* and *Compliance/Quality Support* roles (P=0.004).

#### **Information Sources**

Research participants were asked to rate the frequency with which they used a set of information sources in fulfilling their work role associated tasks (Tables 7.1 and 7.2). A total of 25 information sources where presented, which included sources typical to the pharmaceutical sector. The results indicated that *Procedures* (mean value=3.99), followed by *Colleagues* (mean value=3.93), and *In-house Documentation* (mean value = 3.91) scored the highest frequency across all respondents. *Corporate Intranet* sites were also considered to be

frequent information sources (mean value=3.63), particularly for *Process Technology/Process Development* roles (mean value=3.93). *Personal Memory* (mean=3.64), *Personal Files* (mean=3.41) and the *Internet* (mean value=3.40) were other sources which were used with moderate frequency.

A closer examination of the results revealed that different work roles influenced the degree to which pharmaceutical professionals used different information sources. For example, *Health Authority Regulations – HPRA, FDA and Other such Agencies* (mean value=4.38) were frequently used to address information needs stemming from *Regulatory Support* roles (such as the preparation of registration and market authorisation documentation, regulatory submissions) and *Quality/Compliance Support* roles (mean value=3.89). *Engineers,* on the other hand, indicated greater reliance on Personal Memory (mean=3.81) when compared to other roles.

From the results obtained, *Conference Proceedings, Professional Associations and Standards Organisations* were not considered to be frequently used sources of information across all pharmaceutical professional groups, with mean values of 2.00, 2.37 & 2.47 respectively.

#### Cross-group comparisons: information sources

Kruskal-Wallis comparative statistical analysis was performed to explore the association of the four role groups with the different information sources used. The null hypothesis ( $H_o$ ) stipulated that there would be no difference amongst the four groups (where P > 0.05). A significant difference was observed for *Health Authority Regulations – HPRA, FDA and Other such Agencies* (P=0.001) and *External Sources* (P=0.042).

#### {Please place Table 6 about here}

Post Hoc testing using Mann Whitney U test for non-parametric data was performed to determine where these differences exist (where P<0.05) for each of these information sources. *External Sources* post hoc testing indicated significant differences between a) *Process Development/ Technology* and *Compliance/Quality* (P=0.003) and b) *Process Development/ Technology* and *Compliance/Quality* Engineering (P=0.020).

*Health Authority Regulation* post hoc testing indicated significant differences in: a) *Engineering* in relation to both *Compliance/Quality* (P=0.017) and *Regulatory Support* (P=0.033), and b) in *Process Development/Process Technology*, again, in relation to *Compliance/Quality* (P=0.015) and *Regulatory Support* (P=0.004).

#### 'Information Influencers' on the choice of information sources

In relation to pharmaceutical professionals using different information sources in fulfilling their work role associated tasks, the most influential factor observed across all respondents was *Trustworthiness* (mean value = 4.05), followed by *Quality* (mean value = 3.96), and *Prior Success with a Source & Familiarity of Source* both with mean values of 3.93. The factors of *Knowledge of Various Sources, Accessibility, Convenience/Usefulness and Personal Contact to Source* (mean values of 3.81, 3.76, 3.77 & 3.45 respectively), were rated of average and above average significance as influencers in information source selection. Lower mean values were observed for *Cost, both monetary* (mean value = 2.46) and on the basis of *time & effort* (mean value=3.10) (Table 8).

#### **Cross group Comparisons: Information Influencers**

Kruskal-Wallis comparative statistical analysis indicated no significant differences in terms of information influencers across the groups, suggesting that no probable difference exists within the groups in term of the factors influencing their choice of information source.

#### Enablers to information sharing

Enablers to information sharing were defined as factors influencing the level of information sharing required to perform work related tasks and they included a number of constructs (Table 9). A 5-point Likert scale was used (with 1 indicating 'strongly disagree' and a value of 5 indicating 'strongly agree'), exploring the mean value of each enabler for each working group category, and across all respondents in total.

High levels of importance were assigned to the availability of *Subject Matter Experts* (mean value=4.10), with agreement levels ranging from 3.96 (mean value for Quality/Compliance Support) to 4.75 (mean value for Regulatory Support). These results suggest that the pharmaceutical professionals were engaged in a positive level of information sharing, which could assist in developing a creative and innovative working environment. High Levels of agreement were also observed for *Reliable Internet Access* (mean value = 4.02) and *Access to Online Information Sources* (Mean value=4.01). In addition, high levels of agreement were noted in relation to '*Intranet Site Navigation is User-friendly*' (mean value=3.99), with group means ranging from 3.78 for *Engineering* to 4.50 for *Regulatory Support*. Finally, *Training in Available Information Resources* (Mean value=3.56), *Adequate Time to Share information* (Mean value=3.66) and Organisational Structure Facilitates Sharing (mean value=3.72) achieved a slightly less important value (Table 9).

#### **Cross group Comparisons: Sharing Enablers**

When Kruskal-Wallis comparative statistical analysis was performed on information sharing enablers, results indicated a difference (i.e. P < 0.05) for both *Reliability of Internet Access* (P = 0.019) and *Access to Online Information Sources* (P=0.013). To identify which of the four groups were different, Post Hoc testing using Mann Whitney U test for non-parametric data was performed.

In relation to *Reliability of Internet Access,* comparative testing indicated a probable difference existing (p <0.05) for the following three group pairings:

- Engineering and Regulatory Support (P = 0.020)
- Process Technology/Process Development and Quality/Compliance (P = 0.031)
- Process Technology/Process Development and Regulatory Support (p = 0.026)

In respect to *Access to Online Information Sources,* comparative testing indicated a probable difference existing (p < 0.05) for the following four group pairings:

- Engineering and Regulatory Support (P = 0.028)
- Process Technology/Process Development and Quality/Compliance (P = 0.039)
- Process Technology/Process Development and Regulatory Support (P = 0.001)
- Quality/Compliance and Regulatory Support (P = 0.019).

#### Discussion

#### Information needs triggers

The results of this study demonstrated that for the different information needs triggers high frequency overall mean scores were obtained across different pharmaceutical roles in relation to High Degree of Urgency, High Degree of Complexity and Decision-Making situations. This could be, arguably, explained as the product of the high performance and target date driven working environment within the pharmaceutical sector. According to Leckie (2005), working within a high-performance target driven, time-constrained 'Right First Time' (RFT) working environment, may have a particular contextual impact upon the urgent nature of information triggers. In relation to the context of this study, Torkko et al., (2014) support that "Price pressure and stiff competition are driving the pharmaceutical industry towards greater efficiencies, higher quality, and continuous improvement. It is not only important to perform procedures "right the first time (RFT)" but also without delays and additional costs, associated with errors or losses (p.175). The ICH guidelines Q10 (European Medicines Agency, 2015), emphasise the importance of "continual improvement of process performance and product quality" with specific "lifecycle stage goals" including, among others, pharmaceutical development which meets of a complex user basis addressing effectively "the needs of patients and healthcare professionals, and regulatory authorities and internal customers' requirements", technology transfer between manufacturing sites which requires "control strategy, process validation approach and ongoing continual improvement" (p.10) which may further elaborate the participants' high frequency results in the above areas. The complexity of pharmaceutical information use is also highlighted by Bawden & Robinson (2011) who mention a variety of end groups, including scientists, marketers, regulators, purchasers, other health professionals and the general public. More particularly, and in relation

to the different pharmaceutical roles identified in this study, respondents' data revealed that Decision-Making information triggers together with Problem Solving, were mostly prominent in Process Technology/Process Development and Quality/Compliance Support and Process Technology/Process Development. These roles may include plant operational activities, performance improvement, resolution of technical issues, production system troubleshooting & root cause analysis, with subsequent process improvement initiatives. They are closely aligned with, if not embedded in, production operations, which may suggest a dynamic environment and a pressurized, time-constrained work setting, predisposed to high urgency situations and decision-making. These roles present an environment that is rich in decision-making and problem-solving situations and has a high degree of complexity. Quality/Compliance Support roles may include quality oversight and approval of site procedures, deviation reports and response preparation to address inspection authority observations (the content of which can be highly technical), final batch record approval, critical decisions related to batch disposition (to hold, quarantine, or release a batch for distribution), all performed under a target date driven, high intensity environment supporting site production activities. 

High Degree of Urgency was the most frequent trigger within Regulatory Support roles, followed by Document Preparation, High Degree of Complexity and Decision-Making. Urgency is frequently encountered in preparing documentation which may require regulatory, technical and scientific document review and preparation with strict deadlines. Examples may include the preparation of global regulatory submission documentation, the preparation & processing of change control documentation and the processing of legalisation documentation. This may reflect work that is conducted in collaboration with different site departments (such as the Production, the Quality or the Engineering departments) which could include the performance of license check requests.

In relation to *Engineering* roles, the most frequent triggers were, again, *Decision-Making*, *High Degree of Urgency* and *High Degree of Complexity*. The frequency with which these triggers present themselves may be explained when the nature of the pharmaceutical engineer role is considered more closely. For example, for an engineer involved the installation & commissioning of a new build production facility, daily decision making is required to facilitate the execution of complex projects, which are guided by strict project timelines. This is typical for engineers working within the pharmaceutical sector involved in the execution of new build or building upgrade projects, where up-to-date information is required to allow informed decision making at the various stages of a project and move from completion of one stage to the progression of the next stage.

A less frequent information needs trigger across the different roles was *Production Planning* and specifically in relation to Engineering roles. The low result obtained demonstrates that production planning may not be a primary responsibility for Engineers within the pharmaceutical sector. Those working within a live production plant are engaged in preventative maintenance and facility equipment breakdown support. This may result in a limited need for production planning information to facilitate preventative maintenance planning. On the other hand, the result for Process Technology Development, which achieved a moderate frequency level, reflects a closer alignment with the production department and production planning activities. The second, below average frequency result, which was obtained in relation to Administration Tasks within Engineering related processes could be indicative of administrative tasks having a secondary focus. However, this may not apply to those holding managerial engineering positions, who typically engage with these tasks. Of the 37 engineers surveyed in this study, only 13 described their role as being supervisory or in senior / middle management. Therefore, the results may be indicative of the nature of core work functions of the participants and not necessarily of a situation that is encountered across all engineering related roles. 

Group comparisons across the four pharmaceutical professional roles identified the influence of roles on information needs triggers. For example, *Production Planning* differences between *Engineers* and *Process Development/Technology* roles and between *Engineers* and *Compliance/Quality Support* roles were identified. Differences may stem from the expected nature of these roles, i.e. those engaged in engineering are less

involved in production planning activities. These findings resonate with previous research conducted with other professional groups. For example, Du Preez & Fourie referred to the link of "the specific information sources used by consulting engineers...to particular work roles and tasks during the different stages of an engineering project" (2010 p. 73) and that their "requirements in respect to information content and form influences his or her selection of information sources2 (2010, p. 73).

#### Information sources

Research participants' most frequent use of information sources in fulfilling their work role associated tasks included Procedures, Colleagues and In-house Documentation, followed by Personal Memory and Personal Files. The reliance on Procedures as the most frequently mentioned source should be considered in the context of the environment in which pharmaceutical professionals work. The pharmaceutical industry is a highly regulated sector. The quality and efficacy of pharmaceutical products affect the individuals who use them. Within the context of this research, agencies such as the HPRA (Health Product Regulatory Authority of Ireland), or FDA (Food & Drug Agency of the US) and the MHRA (Medicine and Healthcare products Regulatory Agency of the UK) regulate the guality of pharmaceutical products manufactured in Ireland, with GMP (Good Manufacturing Practices) regulatory standards ensuring pharmaceutical quality. The European Union Council Directive states that "All medicinal products for human use manufactured or imported into the Community, including medicinal products intended for export, are to be manufactured in accordance with the principles and guidelines of good manufacturing practice" (Official Journal of the European Union, 2003). The Medicine and Healthcare Regulatory Agency deems that GMPs are the "minimum standard that a medicines manufacturer must meet in their production processes" (2017). The International Society for Pharmaceutical Engineers (2017) states "A GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product." The foundations of such a system, whose purpose is to build quality into products, is built on procedures. Thus, for those working within such a manufacturing environment, reference to procedures on a daily basis, for all product production and quality testing, quality compliance & regulatory support functions, process development and engineering activities, is required. The use of procedures and their frequency of reference across all four groups is, therefore, a consequence of the pharmaceutical manufacturing environment and the regulations governing this sector.

The reliance on *Colleagues* as information sources in this study has been observed many times previously, for example, in the review of professionals by Leckie et al (1996) and in Kwasitsu's (2003) study of engineers, which found that "co-workers...own business groups" are highly important sources of information (2003, p. 467). Allard *et al.*, (2009), in their study of technical professionals working within high technology firms, similarly, concluded that engineers relied heavily of internal sources such as colleagues. Furthermore, colleagues are important sources of verbal information and facilitators in the process of finding relevant document sources (Allard *et al.*, 2009, p. 444). Several other reasons have been identified in the literature. For example, "(a) Colleagues can provide feedback, either as trusted sources or as impetus for creative solution; (b) a colleague's memory might be the only access point to field documents, and (c) close relationships with colleagues enable the selection of trustworthy experts within a particular subject domain" (Lu & Yuan, 2011, p. 137).

In-house Documentation, which would include (but not limited to) evaluation, commissioning & validation reports, license documentation, position papers, technical reports, specification documents and engineering drawings, was also considered a significant source of information in this study. Allard *et al*, (2009), in their study, also found a heavy reliance on internal sources including "institutional document repositories and existing drawings" (p. 451).

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Although Personal Files and Personal data were frequently used sources, they were not deemed by pharmaceutical professionals as the most prominent ones. Previous research by Kwasitsu's (2003) with engineers, found that 60% of respondents considered personal files and personal memory to be very important information sources. Additionally, Leckie et al., (1996) found that different types of professionals value their personal collections and would use them even if information within them is limited, because they are considered the most easily accessible (p. 186).

The Internet was also a frequently used source but the use of the Corporate Intranet Site was used more prominently, particularly for Process Technology/Process Development. The intranet provides a gateway to 12 corporate technical reports, procedures, policy documents or corporate "institutional document repositories" 13 (Allard et al., 2009, p. 451), necessary to assist in product transfers and troubleshooting tasks, as part of their 14 work roles. Essentially, a corporate intranet source can be viewed as an extension of internal information sources, particularly for those working in a global corporate setting. 16

From the results obtained, Conference Proceedings, Professional Associations and Standards Organisations were not considered to be significant sources of information across all pharmaceutical professional groups. The use of Scholarly Journals was also rated on the basis of below average frequency. This finding coincides with previous research of other professionals, for example, by Kwasitsu (2003), who found that manufacturing engineers consider the use of external conferences and scholarly journals as less important.

A closer examination of the results indicated that professionals in different pharmaceutical roles used External Information and Health Authority Regulation sources with different frequency. In effect, a clear difference exists between pharmaceutical professionals engaged in Compliance/Quality Support and Regulatory Support (highly documentation driven tasks), on one side, and those professionals involved in Engineering and Process development/process technology (process and operational roles), on the other, pointing to the influence of roles on information choices.

#### Information influencers

The most influential factor in relation to different information sources that allowed professionals to fulfil their work across all respondents was Trustworthiness, followed by Quality, and Prior Success with a Source & Familiarity of Source. Other important factors included Knowledge of Various Sources, Accessibility, Convenience/Usefulness and Personal Contact to Source. However, Cost, both Monetary and Time & Effort were less important. Prior Success and Familiarity as well as Knowledge of Sources could be linked to what Du Preez & Fourie (2010) names as "awareness of information", a process which "implies information literacy skills on the part of the user" (p.83). These results should also be, again, considered in context, and particularly within a highly regulated pharmaceutical manufacturing environment, where quality systems & related standards to reflect "strict regulatory control" (Torkka, 2014, p. 176). Consequently, it should not be surprising that factors such as trustworthiness and quality are chosen, as they convey ideas of accuracy and reliability. Accurate information is considered of paramount importance within the pharmaceutical sector, and is required at all times in decision making processes to build and continuously maintain the various quality systems within a pharmaceutical company, necessary to produce medicinal products. Source quality could also be extended to interpersonal information sources who were found to be frequently used by professionals in this study (Woudstra & van den Hoof 2007, p. 1267).

**Enablers to information sharing** 

High levels of agreement in relation to *Enablers of Information Sharing* were observed in relation to *Subject Matter Experts*. These results suggest that the pharmaceutical professionals valued expertise as a positive and valuable information exchange activity. High levels of agreement were also observed for *Reliable Internet Access* and *Access to Online Information Sources*. These results highlight the importance placed on information technology in facilitating information sharing in the course of different work roles and associated tasks and are in line with previous research that also highlights the value that pharmacists place on accessing internet information sources (Kostagiolas, Aggelopoulou, & Niakas 2011). The group comparison testing for *Access to Online Information Sources*, however, suggested that those working within *Process Technology/Process Development* roles, (and to a lesser degree those in *Engineering* and *Quality/Compliance* roles), considered *Access to Online Information Sources* as facilitating information sharing to a lesser degree than those in *Regulatory Support* roles. In addition, the *Regulatory Support* group perceived very high levels of agreement across all sharing enabler variables.

High levels of agreement were also noted in relation to *Intranet Site Navigation is User-friendly'*, which facilitates information retrieval, and online sharing. An accessible and easy way to use the intranet site, supports information and knowledge management (KM) within a company through the organisation and dissemination of information pertaining to company issues. Ruppel & Harrington (2000) establish a further argument based on the organisational intranet facilitating communication and interaction and creating a "knowledge connection": "KM and intranets are closely linked, with intranets enabling KM because of their ability to connect people" (2000, p. 38).

Closer examination of the group comparison testing for *Reliability of Internet Access*, suggested that those working within *Process Technology/Process Development* roles, and to a lesser extent those in *Engineering* roles, consider this enabler to effect to a lesser degree the facilitation of information sharing as part of their work role associated tasks, possibly stemming from their high level of process / operational and plant involvement, i.e. an environmental component. Conversely, those engaged in *Regulatory Support and Quality/Compliance roles* consider this enabler to facilitate information sharing to a greater degree, in fulfilling their work role associated tasks.

In relation to other enablers *Training in Available Information Resources*, *Adequate Time to Share Information* and *Organisational Structure Facilitates Sharing* were also noted by the participants. These findings are in par with previous research that has similarly identified lack of time of pharmacists as a barrier to accessing information (Kostagiolas, Bairaktaris and Niakas, 2010). If we consider these results in conjunction with the earlier information sources results, on the basis of the frequency of using *Forums/ Meetings/Seminars/ Working Groups* as well as *Corporate Network Communities*, where, overall, below average values were obtained, perhaps the provision of increased opportunities for information sharing through forums, seminars, meetings and working groups could further enhance information sharing, through fostering communities of practice where individuals to act "as resources to each other, exchanging information, making sense of situations, sharing new tricks and new ideas" (Wenger, 1998, p. 47).

# Conclusion

A paucity of literature exists with respect to the Information seeking behaviour (ISB) of professionals working within the pharmaceutical production sector. The aim of this research process was therefore to investigate the ISB of diverse pharmaceutical professionals (i.e. those professionals directly involved in the production and operation processes, and those providing regulatory, quality & compliance support services to site operations), and to assess the perceived level of support that exists within the sector towards knowledge & information sharing. This research provided new insights into the ISB of pharmaceutical professionals including a greater

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understanding of the context in which they experience information needs which could help to advance the tailored development of information systems and the way in which they help these professionals search, manage and share important information within a highly regulated & high-performance production environment.

The examination of the results of this research which was based on the ISB GMISP model components, developed by Leckie et al. (1996), i.e. information triggers, information sources and information source influencers with four pharmaceutical professional sub-groupings, points to largely echoed previous findings 10 which suggest that individual work role associated tasks prompt particular information needs. Further to this, 11 12 work role associated tasks have a bearing on information source selection. Therefore, upon reflection, this 13 empirical research provides further support for the relevance of Leckie et al. GMISP model (1996) as a suitable 14 framework to facilitate further examination of the ISB of pharmaceutical professionals working within a 15 production environment. 16

17 In relation to information & knowledge sharing, results obtained suggest that the pharmaceutical professionals 18 surveyed are engaged in positive levels of information & knowledge sharing, through their reliance on 19 procedures, other colleagues and internal documentation as information sources. The participants also 20 indicated a high level of agreement in respect to the value of Available Subject Matter Experts as information 21 22 sharing enablers. Organisations should therefore aim to create opportunities for adequate time to share 23 information and organisational structures, overall facilitating an organisational culture of sharing. A focus on 24 information sharing through forums, seminars, meetings and working groups could enhance information 25 sharing, through the development of communities of practice. 26

"Contextual factors" referred to by Leckie (2005), were present in this study as a highly regulated pharmaceutical production environment and illustrated through a number of avenues: the pharmaceutical professionals' reliance on procedures as a frequently used information source, and their placement of trustworthiness and quality as their top information source influencing factors. Furthermore, the study demonstrated that working within a high-performance target driven time-constrained production environment, brings a particular contextual impact, where frequent urgent information triggers are experienced. These contextual factors and their impact on working within a pharmaceutical production environment, and on the information seeking behaviours of those working in such a setting, warrants further investigation, especially as pharmaceutical professionals aim "towards greater efficiencies, higher quality, and continuous improvement" and it is "crucial to do things right the first time (RFT) without a time delay and without incurring extra costs caused by losses and rejected batches" (Torkka et al., 2014, p. 175).

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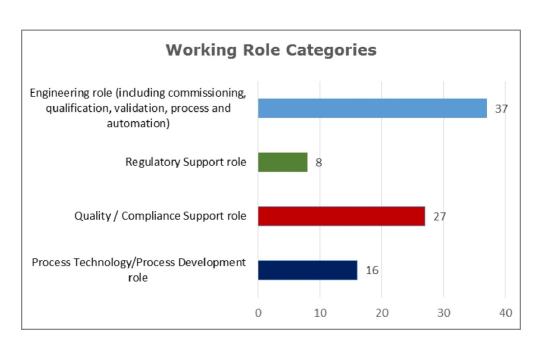
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411x247mm (96 x 96 DPI)

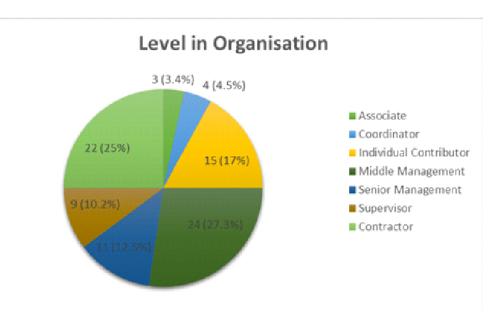
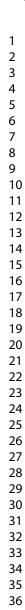


Figure 2. Work role levels within the organisation

541x317mm (38 x 38 DPI)



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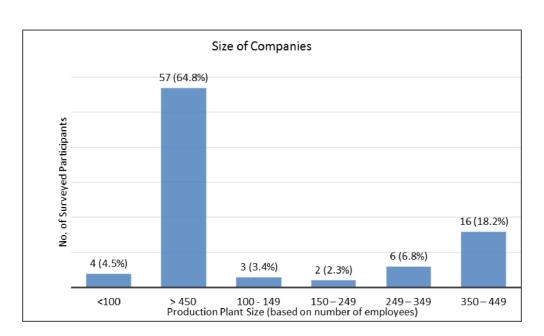
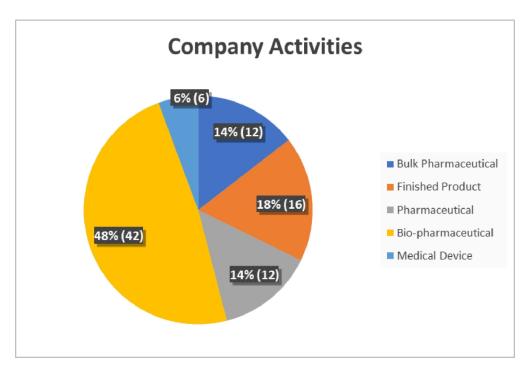


Figure 3. Number of survey participants versus plant size

1151x674mm (38 x 38 DPI)





	Associated Tasks
Regulatory Support	<ul> <li>Preparation of global regulatory submission documentation.</li> <li>Preparation &amp; compilation of marketing authorisations.</li> <li>Change control management.</li> </ul>
Quality/ Compliance Support	<ul> <li>Procedural &amp; regulatory compliance activities.</li> <li>Auditing activities.</li> <li>Production support activities from batch record issuance, review and control.</li> <li>Raw material release activities for batch production to product testing.</li> <li>Product release.</li> </ul>
Engineering	<ul> <li>Support of day to day operations, including preventative maintenance and breakdown support on existing equipment.</li> <li>Commissioning, activities and validation of equipment &amp; building upgrade projects, and new-build projects.</li> <li>Start-up of a new production facility, their role may require performing multiple tasks: new equipment &amp; system design specifications, their installation, calibration, commissioning and validation.</li> </ul>
Process Technology/ Process Development	<ul> <li>Optimisation of plant operations and systems.</li> <li>Design of process equipment, including equipment start-up, qualification, operations, performance improvement, maintenance and resolution of technical issues.</li> <li>Production system troubleshooting and root cause analysis.</li> <li>Identification of process improvement and waste reduction opportunities.</li> <li>Technical transfer activities.</li> <li>Recording key technical product knowledge.</li> <li>Support &amp; development of operational standards of work.</li> </ul>

Table 1. Associated Tasks within the Pharmaceutical Sector

539x534mm (38 x 38 DPI)

# **Information Awareness Factors**

- Source familiarity
- Prior success
- Trustworthiness
- Cost
- Monetary
- Time
- Effort (including both psychological and

physical)

Table 2. Information Awareness Factors

503x331mm (38 x 38 DPI)

Information Sources Characteristics											
<ul> <li>Formal / Informal sources</li> </ul>	<ul> <li>Quality Attributes of source</li> </ul>	- Accessibility of									
<ul> <li>Internal / External sources</li> </ul>	i. Accuracy	source									
– Written / Oral / Personal	ii. Specificity										
sources	iii. Reliability										
	iv. Relevance										

#### Table 3. Information Sources Characteristics

511x163mm (38 x 38 DPI)

Information Outcomes											
Successful information seeking (tasks completed): <ul> <li>procedures preparation and approval</li> <li>completion of specifications</li> <li>regulatory changes</li> <li>authorisation reports</li> <li>license check inquiries</li> <li>closeout of audit observations.</li> </ul>	Unsuccessful information seeking: – Further information seeking or feedback loop – Knowledge gained may benefit another task or role.										

Table 4 Information Outcomes

600x217mm (38 x 38 DPI)

Participant's Geno	ler, Age and Level of I	Education
	Frequency	Percent
Total no. of participants	88	100.0
Female	30	34.1
Male	58	65.9
18 to 24 years	1	1.1
25 to 34 years	7	8.0
35 to 44 years	31	35.2
45 to 54 years	44	50.0
> 55 years	5	5.6
Certification	3	3.4
Diploma	4	4.5
Degree	35	39.8
Graduate Diploma	12	13.6
Masters	25	28.4
PhD	9	10.2

Table 5. Participants' gender, age and level of education

501x418mm (38 x 38 DPI)

		Inform	nation Ne	eds Trigge	rs Sumi	nary Rep	ort for \	Norking	Role Cate	gories		
Working Role Category	Information Triggers	Problem Solving	Production Planning	Process Improvement	Recurring Task	Unexpected Task	Decision Making	High Degree of Urgency	High Degree of Complexity	Document Preparation	Administration Task	Information Request
Process	Mean	4.25	3.06	3.44	2.86	3.25	4.13	4.06	4.00	3.27	2.56	3.63
Technology /	N	16	16	16	14	16	16	16	16	15	16	16
Process Development	Std. Deviation	.683	1.340	.814	1.027	.775	.719	.772	.730	1.387	.892	.719
Quality /	Mean	3.96	2.74	3.44	3.15	3.48	3.96	3.89	3.74	3.56	3.00	3.37
Compliance	N	27	27	27	26	27	27	27	27	27	27	27
Support	Std. Deviation	.854	1.259	1.013	1.008	1.087	.940	1.013	1.023	1.281	1.144	1.214
Regulatory	Mean	3.13	2.38	2.63	3.13	3.50	3.75	4.00	3.75	3.88	3.00	3.63
Support	N	8	8	8	8	8	8	8	8	8	8	8
	Std. Deviation	1.458	3 1.302	1.408	1.246	.926	.886	.756	.707	.835	.535	.744
Engineering	Mean	3.62	1.89	3.11	3.22	3.35	3.95	3.83	3.70	3.59	2.51	3.50
	N	37	35	36	36	37	37	36	37	37	37	36
	Std. Deviation	.893	1.105	.919	1.333	.919	.780	.971	.909	1.322	1.017	.811
Total	Mean	3.80	2.42	3.23	3.13	3.39	3.97	3.91	3.77	3.55	2.72	3.49
	N	88	86	87	84	88	88	87	88	87	88	87
	Std.	.949	1.288	.997	1.170	.940	.823	.923	.893	1.274	1.017	.926
	Deviation											

Table 6. Information Needs Triggers Summary Report for Working Task Categories

865x548mm (38 x 38 DPI)

Work Role Categories		Technol Developr	ogy/Process nent	Quality / Compliance Support			Regulatory Support			Engineering			Overall		
Information Sources	Mean	N	Std. Deviation	Mean	N	Std. Deviation	Mean	N	Std. Deviation	Mean	N	Std. Deviation	Mean	N	Std. Deviation
Procedures	3.93	15	1.033	4.14	21	1.014	4.00	6	1.095	3.91	32	.995	3.99	74	1.000
Health Authority Regulations – HPRA, FDA and other such agencies.	3.13	16	.957	3.89	27	1.155	4.38	8	.744	2.95	37	1.201	3.40	88	1.209
Health & Safety Regulations	2.63	16	.885	2.74	27	1.059	2.38	8	1.061	2.89	37	1.149	2.75	88	1.064
International Standard	2.56	16	.814	3.37	27	1.115	2.88	8	1.126	3.11	37	1.022	3.07	88	1.048
Industry guidelines	3.06	16	.929	3.59	27	.971	3.50	8	.926	3.30	37	.939	3.36	88	.949
In-House Technical Reports	3.44	16	1.031	3.44	27	1.121	3.38	8	.744	3.31	36	.856	3.38	87	.955
Technical Reports produced by Professional bodies	2.71	14	.825	2.77	26	1.142	2.63	8	.916	2.65	34	.849	2.70	82	.939
Supplier Technical Reports	2.21	14	.975	2.65	26	1.018	2.38	8	.744	2.71	35	.893	2.58	83	.939
Sector Publications	1.79	14	.802	2.41	27	1.118	2.25	8	.707	2.24	34	.654	2.22	83	.870
Scholarly Journals	1.50	14	.760	2.07	27	.917	2.00	7	.816	1.83	36	.811	1.87	84	.847
Professionals Associations	1.79	14	.802	2.50	26	.906	2.50	8	.756	2.47	34	.961	2.37	82	.923
Standards Organisations	2.13	15	.834	2.54	26	1.140	2.00	7	.816	2.65	37	.889	2.47	85	.971
Conference proceedings	1.60	15	.828	2.19	27	.879	2.00	8	.926	2.03	37	.928	2.00	87	902

Table 7.1 Information Sources Summary Report for Working Role Categories\_1

772x507mm (38 x 38 DPI)

	Process Technology/Process Development			Quality / Compliance Support			Regulatory Support			Engineering			Overall		
	Mean	N	Std. Deviation	Mean	N	Std. Deviation	Mean	N	Std. Deviation	Mean	N	Std. Deviation	Mean	N	Std. Deviation
In-house documentation	3.87	15	.834	3.96	26	.916	3.75	8	.886	3.92	37	.862	3.91	86	.863
Corporate Intranet	3.93	15	.594	3.41	27	1.010	3.50	8	1.414	3.71	34	.938	3.63	84	.967
Internet	3.07	14	.997	3.77	26	1.070	3.00	7	.577	3.33	36	.986	3.40	83	1.011
Colleagues	3.73	15	.799	3.92	26	.935	4.17	6	.983	3.97	33	.883	3.93	80	.883
Technical Experts	3.56	16	.814	3.44	27	.974	3.67	6	.816	3.67	36	1.042	3.58	85	.956
Consultants	2.25	16	1.238	2.60	25	1.080	3.00	6	.894	3.00	36	1.095	2.73	83	1.127
Forums / meetings / seminars / working group	2.44	16	1.153	2.70	27	1.235	2.57	7	.787	2.92	37	.924	2.74	87	1.062
Internal Sources	3.69	16	.602	3.59	27	.888	3.43	7	.787	3.54	37	.900	3.57	87	.830
External Sources	2.27	15	.799	3.15	27	.989	3.00	7	.816	2.92	37	1.064	2.88	86	1.011
Corporate Networking Communities	2.44	16	1.094	2.44	27	1.013	2.71	7	1.113	2.76	37	1.140	2.60	87	1.083
Personal Memory	3.69	16	.704	3.48	27	.802	3.29	7	.951	3.81	37	.967	3.64	87	.876
Personal Files	3.56	16	.964	3.44	27	.847	2.86	7	.690	3.42	36	1.131	3.41	86	.987

Table 7.2. Information Sources Summary Report for Working Role Categories\_2

764x435mm (38 x 38 DPI)

			Informa	ation Influ	encers Su	mmary Rep	ort for W	orking Ta	sk Catego	ories			
Working Role	Information Influencers e	Prior Success with source	Famili- arity of source	Trained on info source	Accessi- bility	Knowledge of various info sources	Cost (time/eff ort)	Monetary Cost	Quality	Trustwor- thiness	Currency of Infor- mation	Conven- ience/use fulness	Personal contact to source
Process	Mean	4.00	4.07	3.38	3.80	4.08	2.93	1.92	4.00	3.93	3.42	3.86	3.63
Technology	Ν	15	15	13	15	13	14	12	14	14	12	14	16
Process	Std. Deviation	.655	.594	.870	.775	.641	.997	1.084	.961	.829	.996	.864	1.025
Develop- ment	Variance	.429	.352	.756	.600	.410	.995	1.174	.923	.687	.992	.747	1.050
Quality /	Mean	3.81	3.89	3.30	3.96	3.85	3.12	2.73	3.96	4.04	3.62	3.81	3.27
Compliance	Ν	27	27	27	27	26	26	26	27	27	26	26	26
Support	Std. Deviation	.879	.751	1.031	.759	.613	1.107	.874	.854	.940	.983	.849	1.041
	Variance	.772	.564	1.063	.575	.375	1.226	.765	.729	.883	.966	.722	1.085
Regulatory	Mean	4.13	4.00	3.63	3.63	4.13	3.00	2.38	3.88	4.13	2.88	3.75	3.13
Support	Ν	8	8	8	8	8	8	8	8	8	8	8	8
	Std. Deviation	.835	.926	.744	.744	.641	1.195	.744	.835	.835	.991	1.035	.641
	Variance	.696	.857	.554	.554	.411	1.429	.554	.696	.696	.982	1.071	.411
Engineer-	Mean	3.95	3.89	3.34	3.63	3.62	3.17	2.47	3.97	4.08	3.71	3.71	3.58
ing	Ν	37	37	35	35	34	35	34	35	36	34	34	36
	Std. Deviation	.664	.809	.938	.843	.888	1.071	1.022	.664	.732	.799	.836	1.079
	Variance	.441	.655	.879	.711	.789	1.146	1.045	.440	.536	.638	.699	1.164
Total	Mean	3.93	3.93	3.36	3.76	3.81	3.10	2.46	3.96	4.05	3.55	3.77	3.45
	Ν	87	87	83	85	81	83	80	84	85	80	82	86
	Std. Deviation	.744	.759	.932	.797	.760	1.066	.980	.783	.815	.926	.851	1.025
	Variance	.553	.577	.868	.634	.578	1.137	.961	.613	.664	.858	.723	1.051

Table 8. Information Influencers Summary Report for Working Task Categories

772x497mm (38 x 38 DPI)

Information Sharing Enablers Summary Report								
			Access to			Organisational		
		Reliable In-	online	Intranet site	Adequate time	Structure	Training in avail-	Available Sub-
		ternet Ac-	information	navigation is	to share infor-	facilitates shar-	able information	ject Matter
Working Role Category		cess	sources	user-friendly	mation	ing	resources	Experts
Process Technolo-	Mean	3.56	3.56	3.94	3.44	3.63	3.44	4.13
gy / Process De- velopment	N	16	16	16	16	16	16	16
	Std. Devia- tion	.814	.727	.854	.814	.885	.892	.885
Quality/ Compliance Sup- port	Mean	4.19	4.04	4.15	3.59	3.63	3.67	3.96
	N	27	27	27	27	27	27	27
	Std. Devia- tion	.962	.808	.770	.931	.967	1.038	.980
Regulatory Support	Mean	4.75	4.75	4.50	4.13	4.13	3.75	4.75
	N	8	8	8	8	8	8	8
	Std. Devia- tion	.463	.463	.535	.991	.991	.886	.463
Engineering	Mean	3.95	4.03	3.78	3.70	3.73	3.49	4.05
	N	37	36	37	37	37	37	37
	Std. Devia- tion	.998	.941	1.031	.909	.838	.901	.970
Total	Mean	4.02	4.01	3.99	3.66	3.72	3.56	4.10
	Ν	88	87	88	88	88	88	88
	Std. Devia- tion	.959	.869	.903	.908	.896	.933	.935

Table 9. Information Sharing Enablers Summary Report

778x477mm (38 x 38 DPI)