PRODUCTION OF INDIVIDUALIZED MEDICINES BY ADDITIVE MANUFACTURE (3D PRINTING)

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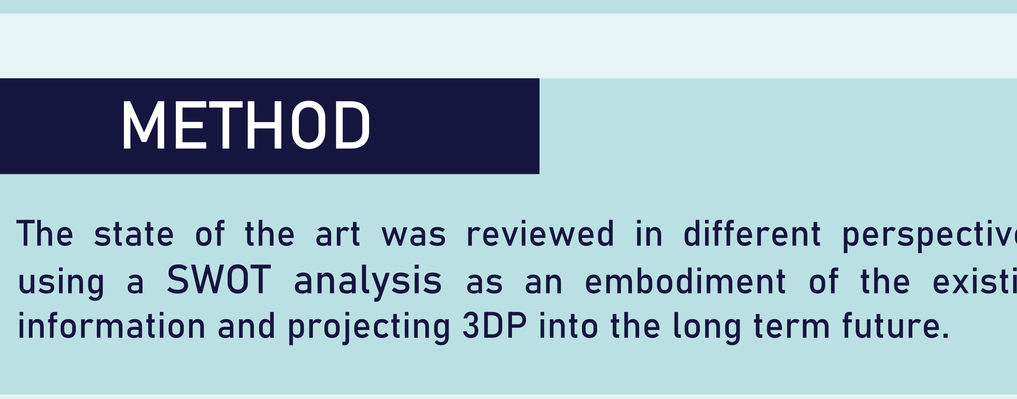
INTRODUCTION

Three-dimensional printing (3DP) is an emerging set of technologies, increasingly explored in the production of customized dosage forms [1-2].

Benefiting from the ongoing digital revolution within healthcare, and the ability to provide higher flexibility than traditional pharmaceutical manufacturing processes, 3DP presents remarkable advantages, but also challenges [1-4].

The co-participation of Health Entities, Pharmaceutical Industry and Compounding Pharmacies, seems to be the best approach for the implementation of 3DP in the pharmaceutical sector.



OBJECTIVE

This work aims at evaluating the advantages and drawbacks of implementing 3DP technologies in pharmacies, towards patient centric manufacturing of medicines.

METHOD

The state of the art was reviewed in different perspectives, using a SWOT analysis as an embodiment of the existing information and projecting 3DP into the long term future.

CONCLUSION

Emergent 3DP of dosage forms can potentially fulfil the goal of personalizing the medicines to the individual patient's needs. Despite the many strengths and opportunities identified, there are still many hurdles to overcome.

The pharmaceutical sector and academia are committed, through research and training, to make production of tailored medicines a reality, while strengthening the pharmacist role as a healthcare provider.

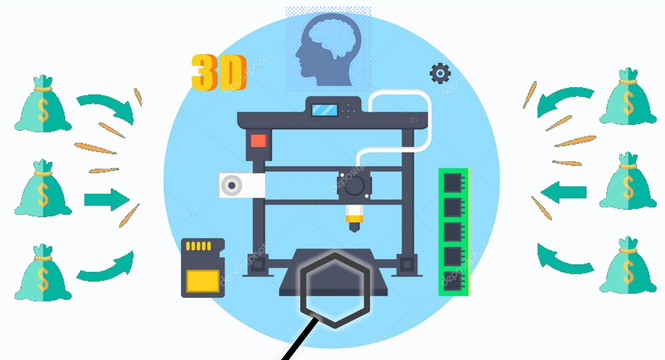
STRENGTHS

Individualized medicines

Medicines with flexible and precise doses, particularly useful to maximize therapeutic outcomes in particular age groups (e.g. paediatrics and geriatrics) and/or diseases (e.g. kidney/hepatic impairment, oncology); for chronic treatments (e.g. multiple drugs into a single dosage form, modulation of the drug release kinetics by adjustment of shape, size and structure), and for rare diseases (e.g. orphan drugs).

- Manufacture closer to patients;
- Scale-up not required;
- Eligibility for implementation in compounding pharmacies;
- Increased role of pharmacists in patient care;
- Overall promotion of pharmacists as service providers.

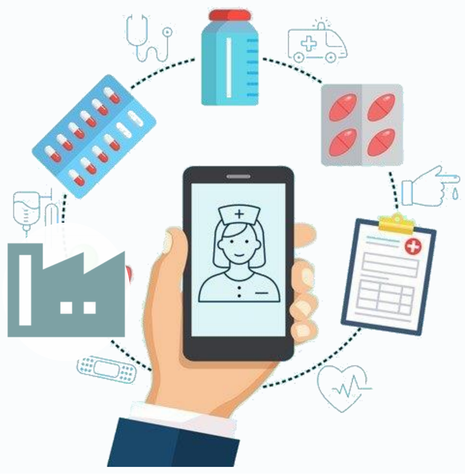
WEAKNESSES



Investment on Qualified Resources

- Trained personnel and technological qualified resources required;
- High initial investment in human and material resources;
- Adaptation of printers to fulfill pharmaceutical regulatory requirements;
- Running costs may increase;
- Daily professional practice must change.

OPPORTUNITIES



Better integration of prescription, production and dispensing of medicines

Strengthen the connection between pharmacist and patient

Benefits in compliance and health literacy

THREATS

Change in professional practice

Co-participation and deep involvement of the medical and pharmaceutical classes in dealing with prescriptions for 3DP medicines. Physicians and pharmacists must change daily practice since medicines are designed, manufactured and prescribed for patients in a different way.

- Lack of expertise may compromise early initiatives;
- Stakeholders may resist to change;
- Specific requirements of the pharmaceutical industry (e.g. equipment qualification; technician training, software and cleaning validation, etc.) have to be considered.

REFERENCES: [1] Ursan I.D. et al. Three-dimensional drug printing: A structured review. J Am Pharm Assoc 2013; 53: 136–144; [2] Alomari M. et al. Personalized dosing: Printing a dose of one's own medicine. Int J Pharm 2015; 494: 568–577; [3] Zhang J. et al. Coupling 3D printing with hot-melt extrusion to produce controlled-release tablets. Int J Pharm 2017; 519: 186–197; [4] Beck R.C.R. et al. 3D printed tablets loaded with polymeric nanocapsules: An innovative approach to produce customized drug delivery systems. Int J Pharm 2017; 528: 268–279.

ACKNOWLEDGEMENTS: Fundação para a Ciência e a Tecnologia, Lisbon (PT) supported this work (PTDC/CTM CTM/30949/2017 | Lisboa-010145-Feder-030949 and SFRH/BD/146968/2019).