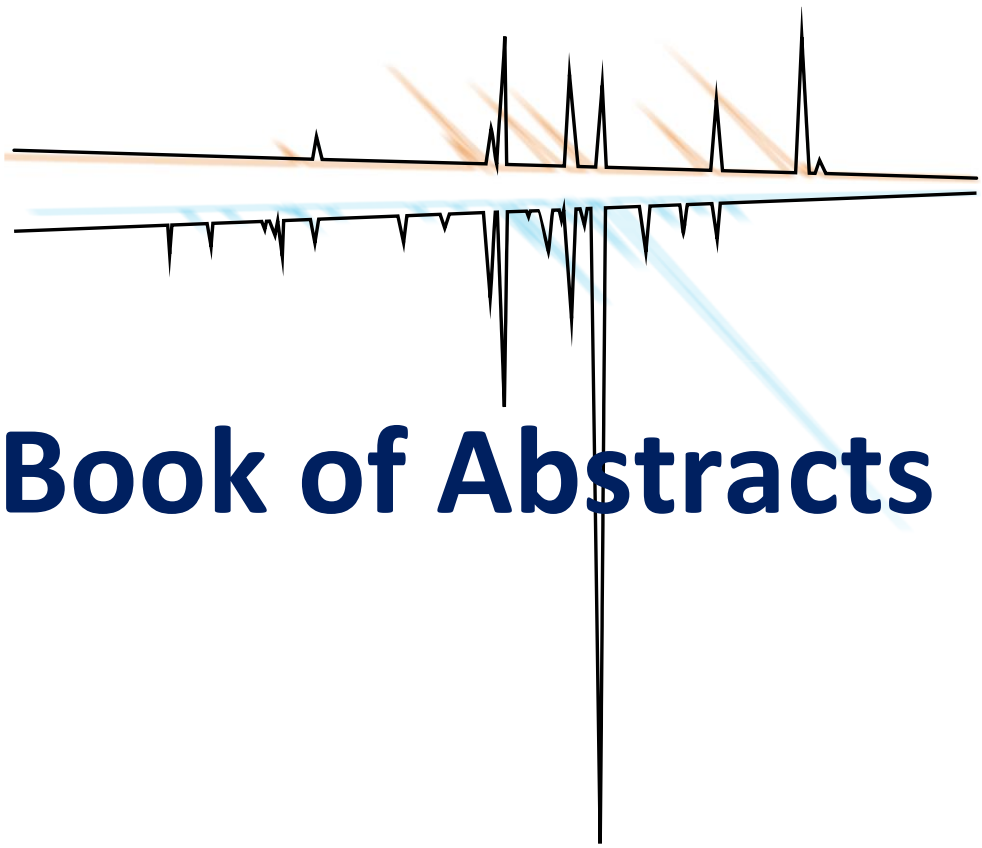
10th IAPC Meeting

Tenth World Conference on Physico-Chemical Methods in Drug Discovery & Sixth World Conference on ADMET and DMPK



Book of Abstracts

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&
Sixth World Conference on ADMET and DMPK
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Bridging science & regulation: quality by design in patient-focused formulation development

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Patient acceptance and usability play a crucial role in achieving successful therapeutic outcomes. Consequently, there is an imperative to incorporate patient-focused formulation design into the pharmaceutical development process, particularly for more vulnerable patient populations such as paediatric and geriatric. This approach aligns with the scientific quality by design (QbD) principle, where products' critical quality attributes (CQAs), as well as critical attributes of the starting materials (CMAs) and critical process parameter (CPPs) are identified and tailored to accommodate patient-related attributes.

A number of marketed products have failed to reach their full therapeutic potential due to insufficient recognition of patients' needs and the characteristics of the treated disease or condition. As a result, science-based patient-focused formulation development is now supported through regulatory programs and guidelines. Advanced data analysis and computational tools are also leveraged to support safety and effectiveness of new drugs. Regulatory agencies frequently convene expert advisory committees comprising scientists, clinicians, and patient representatives to review and evaluate new drug applications. Various approaches to patient-focused formulation development encompass the selection of specific dosage forms and/or administration routes (e.g. orodispersible and chewable tablets, transdermal patches), modified release formulations (delivering drugs over daily to yearly time frames depending on the dosage form), combination products (mostly marketed as fixed-dose combinations of cardiovascular medicines), personalized medicines (customized based on patients' genetic and/or metabolic characteristics), etc. The identification of potential polypharmacy requirements and specific changes in (patho)physiology, metabolism, and excretion, as well as side effects or changes in behavioral traits arising from the disease's progress, should remain some of key drivers for product design. For special patient groups like children, considerations of palatability (including taste masking), dose adjustment, and age-appropriate dosage forms are essential.

Challenges associated with such an approach include heterogeneity of patients, including small sub-populations, and complex process that requires high-risk decision-making during the formulation development. Therefore, fostering scientific evidence and guidance from the early stages of new formulation development, while considering all potential CQAs that might contribute to products' acceptability and usability, is crucial.

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