DRUG PRODUCT DEVELOPMENT CRASH COURSE

12-13 OCTOBER 2023, CRACOW

1. Molecule selection and IP

When selecting the right molecules for the Gx development pipeline, it's essential to thoroughly assess the intellectual property and data exclusivity limitations and also consider all the technical, sourcing, manufacturing, clinical, registration, and business aspects.

It's more prudent to allocate the necessary resources upfront during the evaluation rather than investing in the wrong product.

2. Project management

Project management is vital for Gx drug product development as it ensures efficient coordination, risk mitigation, resource optimization, and compliance with regulatory standards, ultimately contributing to timely and cost-effective product delivery.

Effective project management also facilitates communication, collaboration, and quality control among cross-functional teams, helping companies to navigate the complex and highly regulated Gx drug development process successfully.

3. Preformulation

The preformulation phase is an important bridge between API and drug product development where the transfer of API critical quality attributes, and the understanding of the original drug product by reverse engineering play a critical piece for successful formulation development.

4. Analytical development

Navigating the maze of formulation development without properly developed and validated methods and correctly set specifications is like driving blindfold. The formulation development can hardly do without the analytical development which provides the (in)sight.

5. Formulation development

Formulation development in the Gx industry stems from detailed knowledge obtained during the preformulation stage. However, the path toward a robust formulation process that covers all critical attributes of the drug product may still be full of thorns, and the formulation expert must still be on the lookout.

6. Clinical trials

Clinical experts are working in close contact with the technical team during all phases of the drug product development. Finally, they are responsible for designing the appropriate clinical setting including all parameters to achieve statistically significant results and prove clinical relevance.

7. LC-MS techniques

The medicine produced must be effective and, above all, safe for the patient. The LC-MS technique is used to identify product and process contaminants, both for small molecules and multimolecular compounds. Using the LC-MS technique, the safety of drugs and their equivalents for the patient can be demonstrated. Also important are the possibilities this technique offers from the development phase to quality control and release methods, as well as its advantage during qualitative and quantitative analyzes in relation to currently used methods. There will also be the current approach of regulatory agencies to the methods used and how the LC-MS technique compares to them.

8. Laboratory of Chromatography and Mass Spectrometry JCI as laboratory involved in drug development process

The laboratory specializes in method development and method validation of API identification, API content determination, impurities content. Among others the offer consists residual solvent test, dissolution tests - release profile testing, disintegration time tests and other studies of the drug form. The laboratory also performs analysis of raw materials e.g. particle size analysis by laser diffraction. Stability tests and quality control analysis are involved in laboratory offer as well.

The new direction of the laboratory development are permeability tests using Franz chambers. In the field of protein drug development, the laboratory offers a service of protein purification and protein analysis e.g. molar mass determination (SEC-MALS).

The laboratory is distinguished by its individual approach to the client's problem.

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