The Analytical Chemist in the pharmaceutical industry

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Drugs

The FDA defines drugs as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals and articles (other than food) intended to affect the structure or any function of the body of man or other animal.

At Roche, they are categorised into different types referring to

Disease treatment:

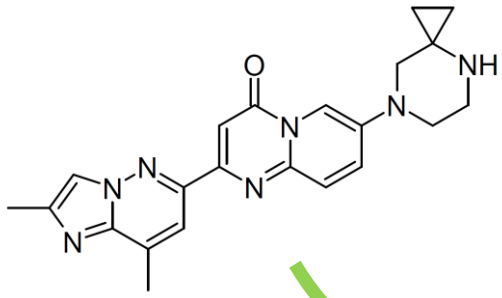
- Oncology
- Neuroscience
- Immunology
- Infectious diseases
- Opthalmology
- Cardio/Metabolism

Structural types:

- Small molecules
- Large molecules
- Cells & Genes
- Antibody drug conjugates

Pharma’s mission

1. Discovers new molecular entities that have impact in human and animal health.
2. Develops the processes to bring the drugs to the market.
3. Ensures patient safety by regular testing and compliance with health authorities.



Analytical chemists

Their role to delivering to patients

Key role in the technical R&D section of the pharmaceutical industry.

Apply Good Practice quality guidelines to ensure quality of the generated results.

<u>Roles include:</u>

- Laboratory analyst (Development support, QC, PAT)
- Analytical Project Leader/Expert/Lab head
- Laboratory systems & support specialist (instrument qualification, systems validation, stability studies organisation)

Equipment and techniques used

Pharmacopoeial methods

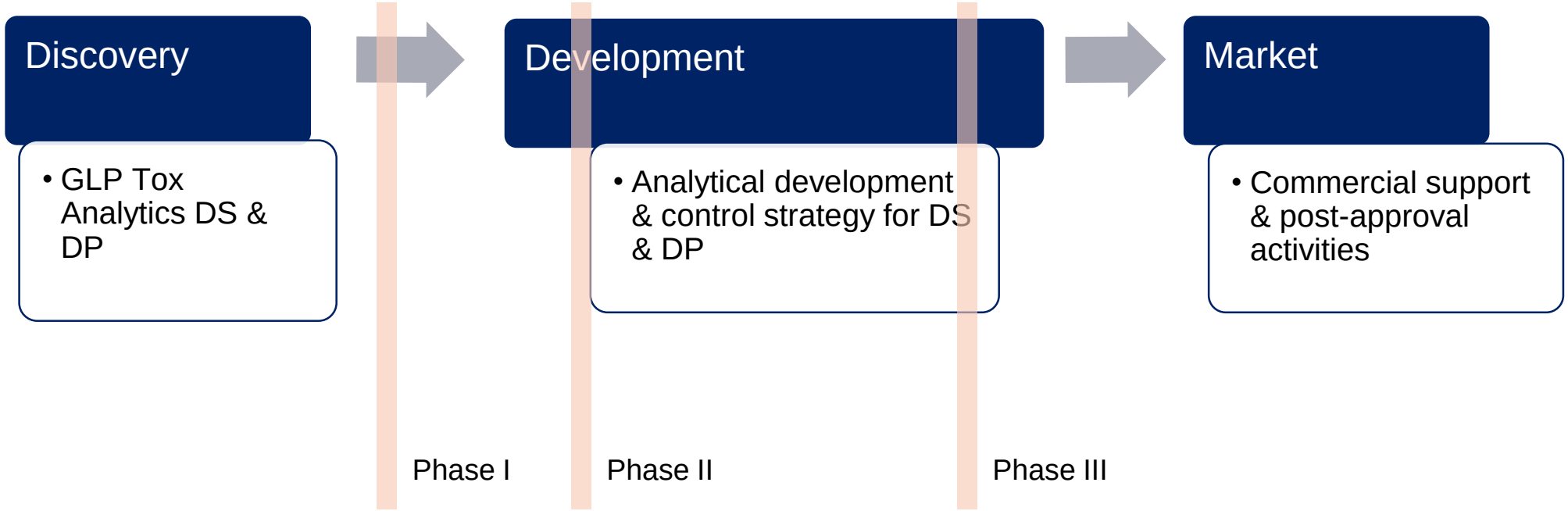
- Dissolution
- Sulphated ash
- Hardness
- Titration
- Microbial enumeration tests (MET)/Sterility
- Visible/sub-visible particles etc

Physicochemical methods

- Chromatography for assay & purity (HPLC, IC, GC, SFC)
- UV-VIS & Fluorescence spectroscopy, CAD, NMR
- Mass spectrometry (LC/GC-MS, ICP-MS)

PTDC-A (Analytical R&D)

- Consisting of approx. 160 employees applying innovative analytical science to synthetic molecules
- Active portfolio of ~40 projects
- Strategic outsourcing of activities to CMOs



PTDC-A (Analytical R&D)

Drug substance / Drug product Analytics

- ✓Method development for starting materials, step products, APIs, DP formulations
- ✓Release of clinical batches according to specifications
- ✓Troubleshooting and structure elucidation of unknown impurities
- ✓Trace analytics for genotoxic, elemental impurities
- ✓Stability studies of drug products

Doing now what patients need next