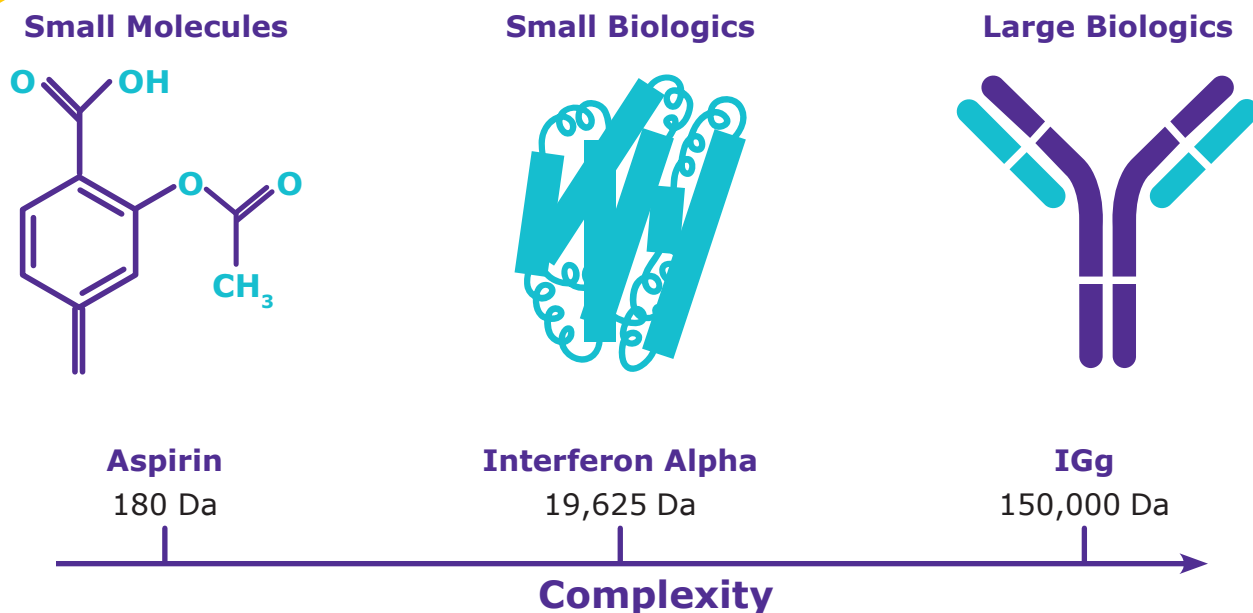


How to overcome the challenges in biologics development & quality control

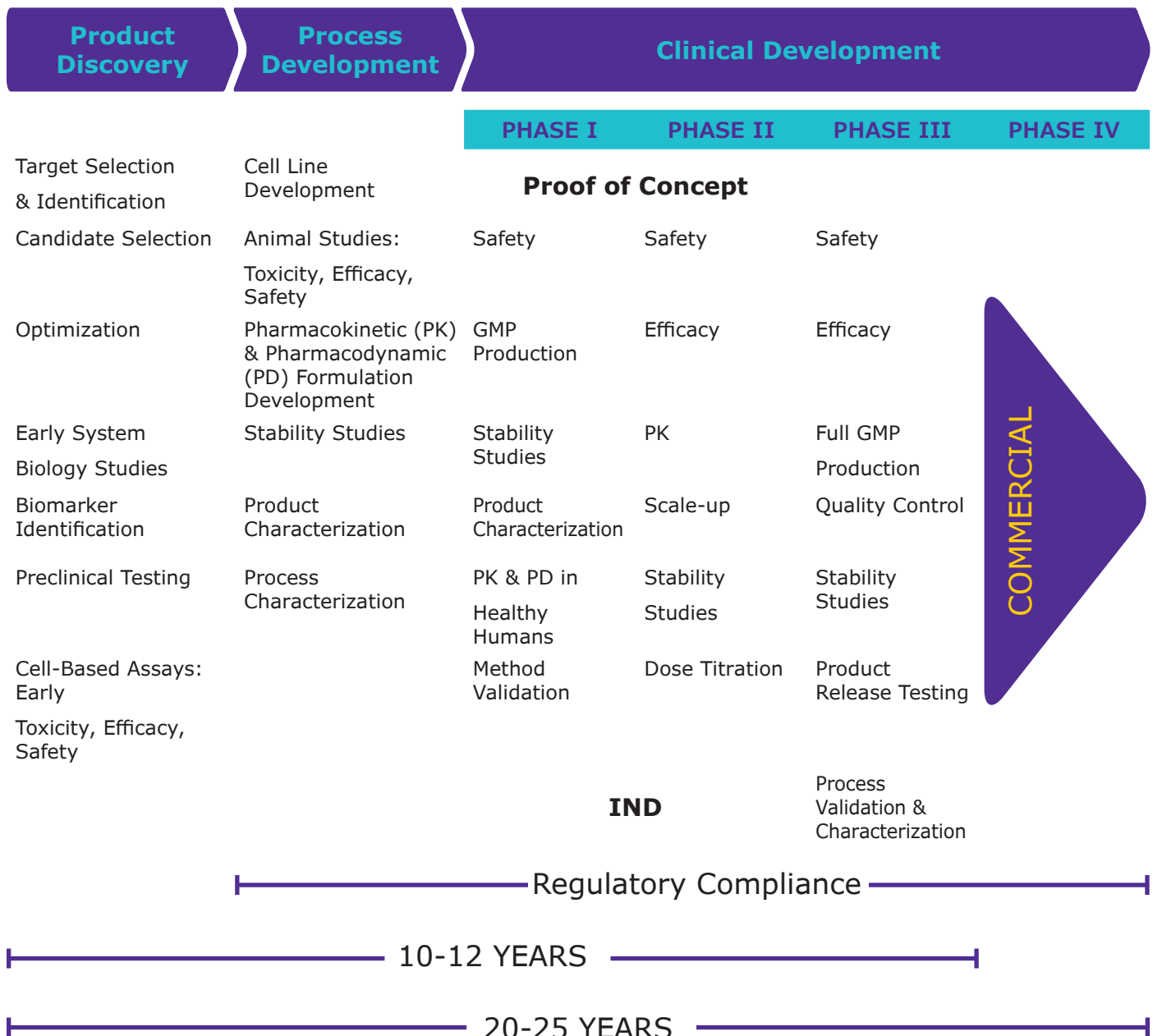
The global biologics market is booming. By 2025, it is expected to reach a value of \$450B. Though biologics are currently celebrating momentum, their development remains greatly challenging. Even small variations in the highly complex structure of biologics can already have an effect on the biologics' safety, efficacy, and function. This can cause severe immune reactions in patients and trigger life-threatening conditions. It is therefore essential to address the challenges in biologics development as early as possible.



Types of Biologics



WORKFLOW OF BIOLOGICS DEVELOPMENT



Biologics development & quality control come with a number of challenges...



If anything in the development of biologics goes wrong, it can result in manufacturing failures, severe time delays, regulatory issues, and risks for the patient. One change triggers a cascade of changes!

How do we support biologics development & quality control?



To prevent contamination, we have

- 40+ years of sterility testing expertise
- Developed the Monocyte Activation Test (MAT) *in vitro* test kits for pyrogen testing, to move away from animal-based tests
- A complete portfolio for microbiology quality control monitoring of air, surfaces, people, raw materials, in-process samples & the final product



To address reference standard challenges, we have

- Developed a comprehensive portfolio of 100+ common impurities often found in extractables & leachables studies



To free more resources for method development, we use

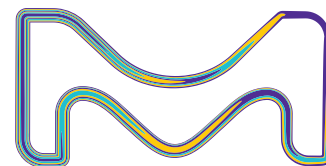
- The SigmaMAb ADC Mimic as a non-toxic drug mimic for mass spectrometry & high-performance liquid chromatography
- The SOLu-Trypsin enzyme for mass spectrometry. SOLu-Trypsin is a convenient, ready-to-use trypsin solution for protein digestion & is stable in solution when refrigerated



To support our customers through the regulatory maze, we

- Have decades of regulatory experience
- Comply with numerous global regulatory standards, e.g. ISO, ACS, USP, PhEur, JP, FDA CFR
- Offer products with a range of specifications & accreditations

Meet our Life Science Brands



Millipore®

The Millipore® portfolio of Merck offers an ecosystem of industry-leading products and services, spanning preparation, separation, filtration and monitoring – all of which are deeply rooted in quality, reliability and timetested processes. Our proven products, regulatory and application expertise are a strong foundation you can rely on to consistently perform at the highest level.

Supelco®

The Supelco® portfolio of analytical solutions of Merck is developed by analytical chemists for analytical chemists to ensure your results are accurate, precise and reproducible. Every product is meticulously quality-controlled to maintain the integrity of your testing protocols and, with our dedicated scientists, the expertise you need is always on hand.

BioReliance®

The BioReliance® portfolio of Merck encompasses biopharmaceutical characterization, safety testing and process development, as well as clinical and commercial biomanufacturing. Our experienced teams and operational expertise make us the partner who supports you all the way and always has your vital goal in mind.

SAFC®

The SAFC® portfolio of Merck offers customized and ready-to-use raw material solutions, backed by deep regulatory expertise. Our high-quality products and services are supported by an experienced and responsive team of raw material and regulatory experts who are committed to understand your requirements and provide tailored solutions that meet your exact needs.

Sigma-Aldrich®

The Sigma-Aldrich® portfolio of Merck offers a strong and ever-expanding offering of lab and production materials. Through our technical support and scientific partnerships, we help connect our customers with a whole world of progress.

Milli-Q®

The Milli-Q® portfolio of lab water solutions of Merck takes care of all your water quality and purity needs. Our solutions are backed by consistent quality and full compliance and work seamlessly together, letting you focus on your vital work.

Our life science portfolio brands have their own unique way of doing things, but all are connected by a common purpose and ambition: solving the toughest problems in life science by collaborating with the global scientific community and accelerating access to solutions that improve health for people everywhere.

Wayne Way, Global Strategy Pharma QC at Merck

Tackle biologics development and quality control now!

Benefit from our expertise and check out our latest educational content and products [here!](#)

List of Acronyms

ACS - American Chemical Society

ADC - Antibody-Drug Conjugate

ATP - Adenosine Triphosphate

DA - Dalton

FDA CFR - Federal Drug Administration
Code of Federal Regulations

GMP - Good Manufacturing Practice

IGg - Immunoglobulin G

IND - Investigational New Drug Application

ISO - International Organization
for Standardization

JP - Japanese Pharmacopeia

mAb - Monoclonal Antibody

PD - Pharmacodynamic

PhEur - European Pharmacopeia

PK - Pharmacokinetic

QC - Quality Control

USP - United States Pharmacopeia

Sources

- California Manufacturing Technology Consulting
- European Medicines Agency, SME Office
- Pharma Focus Asia
- Merck KGaA, Darmstadt, Germany