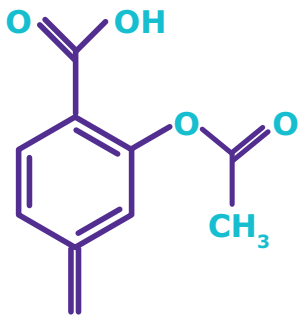
How to overcome the challenges in biologics development & quality control

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.

Small Molecules



Aspirin
180 Da

Small Biologics

Interferon Alpha
19,625 Da

Large Biologics

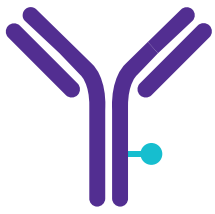
IGg
150,000 Da

Complexity

Types of Biologics

Monoclonal antibodies (mAbs)

Fusion proteins



Antibody-drug conjugates (ADCs)

WORKFLOW OF BIOLOGICS DEVELOPMENT

Product Discovery	Process Development	Clinical Development			
		PHASE I	PHASE II	PHASE III	PHASE IV
Target Selection & Identification	Cell Line Development	**Proof of Concept**			
Candidate Selection	Animal Studies: Toxicity, Efficacy, Safety	Safety	Safety	Safety	
Optimization	Pharmacokinetic (PK) & Pharmacodynamic (PD) Formulation Development	GMP Production	Efficacy	Efficacy	
Early System Biology Studies	Stability Studies	Stability Studies	PK	Full GMP Production	
Biomarker Identification	Product Characterization	Product Characterization	Scale-up	Quality Control	
Preclinical Testing	Process Characterization	PK & PD in Healthy Humans	Stability Studies	Stability Studies	
Cell-Based Assays: Early Toxicity, Efficacy, Safety		Method Validation	Dose Titration	Product Release Testing	
			IND	Process Validation & Characterization	

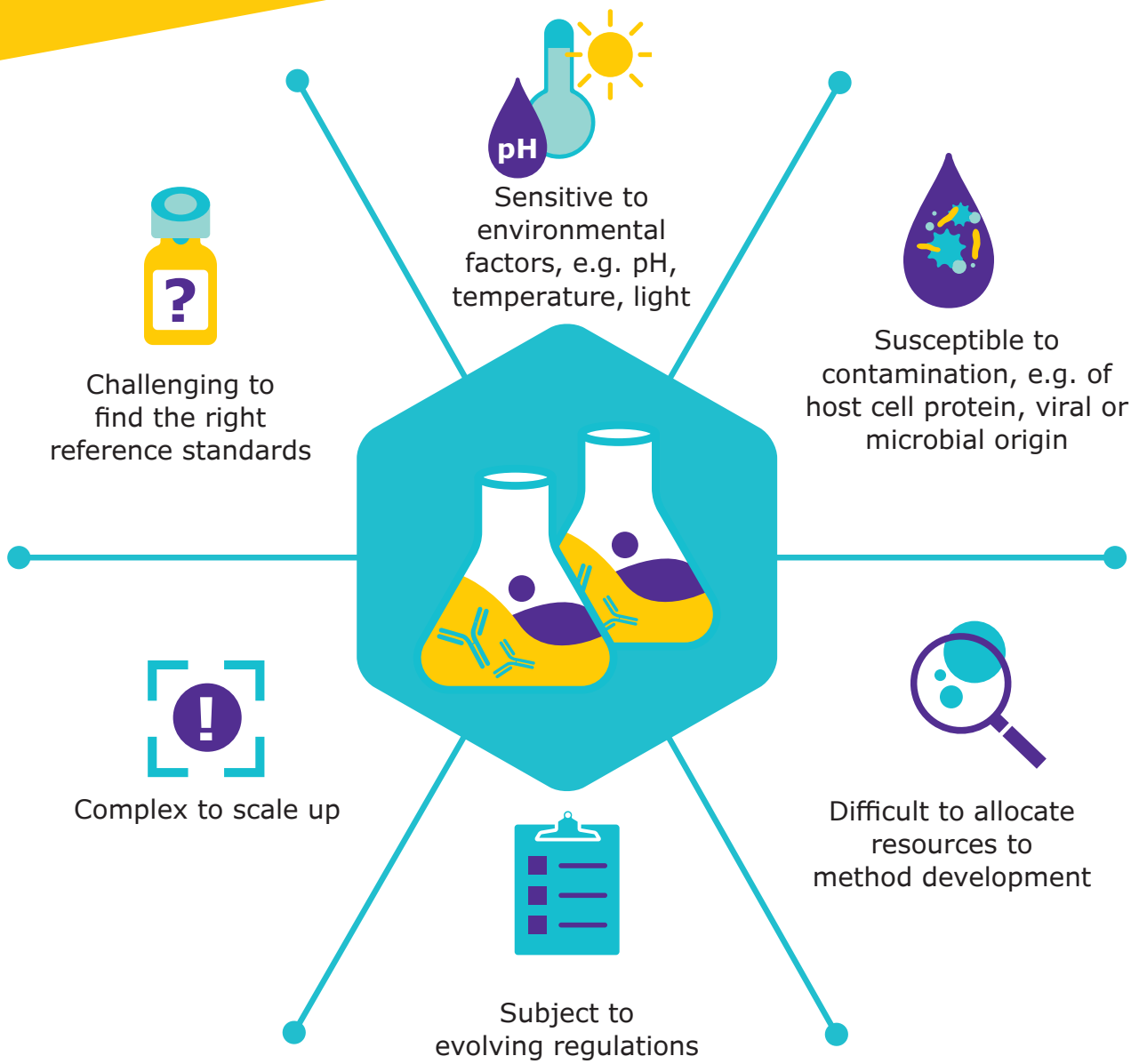
COMMERCIAL

Regulatory Compliance

10-12 YEARS

20-25 YEARS

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 MilliporeSigma 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 MilliporeSigma 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 MilliporeSigma 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 MilliporeSigma 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 MilliporeSigma 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 MilliporeSigma 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 MilliporeSigma

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 - Adensosine 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

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