



QBDC at a glance

Experts of biologics

Engineers for your succes

QBDC at a glance

Our main topics

- ATMP, NBE and Biosimilar Development
- Process Development
- Quality Management & Assurance
- Qualification & Validation

Our services

- Consultancy
- Hands-on work
- Training
- Networking

Our solutions

- METIS - Data Historian
- TEMIS - cGMP DMS & QMS
- EDDI – eipigenetical digital data interface

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Consultancy

- Guidelines and Regulations
- Technical challenges
- Work flows
- Road maps

Topics:

- Medium Development
- CMC Development
- Scale-up and Tech Transfer
- Scientific Advice
- From Facility Layout, Design to Validation & Qualification
- Quality Management & Assurance
- Project Management

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Hands-on work

- Data interpretation
- Performing Audits
- Writing Documents
- Data Management

Topics:

- Establish development plans and dossiers
- Establish CMC / Regulatory roadmaps
- Troubleshooting (e.g. cell culture, product quality)
- Write protocols and/or generate reports
- Write Scientific advice briefing books
- Establish VMP/QMP/ Qualification and Validation Documents
- Implementation of METIS / TEMIS / other DMS and Historians
- Generation of epigenetical process models / digital twin

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| Training

We offer presentations, talks and workshops

Topics:

- GMP for biologics / engineering / projects
- Process development from cell line to finished product
- Characteristics, potential & advantages of biosimilars & biosimilarity
- How to develop an NBE, how to develop a biosimilar
- Material requirements, quality and demands for GMP production
- CMC development
- Scientific background
- IMPD / MAA

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Networking

We are building bridges between technologies and cultures

Topics:

- Helping you identifying partners along your value stream from DNA to release to support your development and manufacturing
- CMO selection / project management
- CRO selection / project management
- Release of product to Europe / Switzerland

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 METIS

 TEMIS



cGMP-compliant document management software:

- Accompany documents from preparation to archival
- Fully Digital Work Flows
- Cost effective
- Easy to implement, easy to train, easy to use

Highly increasing efficiency

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Laboratory data management and analysis software

- Standardized Data Collection
- Data Assessable and Comparable
- Easy to implement, easy to train, easy to use

Analyse ALL process steps with the same care

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EDDI

EDDI - Epigenetical Digital Data Interface

- **Better process robustness**
 - Saves on number of runs
 - Predictive yields and the chance to adapt
- **Less time and costs for development**
 - Up to 30% less time for process development
- **Sustainable benefits of a digital twin**
 - reduction of resources by optimizing the use of nutrients and energy, minimizing waste and improving overall process efficiency

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EDDI – A paradigm shift in bioprocess analysis



Ready-made tools

Biosimilar Risk Assessment

- *Comprehensible chart to support the decision-making process of finding the optimal Biosimilar molecule*

ATMP Risk Assessment

- *Comprehensible system to perform guideline conform ATMP assessments*

CDMO Selection Guide

- *Structured guideline for questioning, scoring and comparing most suitable business partners*

Facility Cost Calculator

- *Customizable spreadsheet to weigh up the effort, costs and pros/cons of single-use versus stainless steel facilities*

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Customers



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