

The logo for Quality Biotech Development & Cells (QBDC) is centered on a white, irregular brushstroke background. The letters 'qbdc' are in a bold, blue, lowercase sans-serif font. The 'q' has a long, thin vertical tail that extends downwards.

qbdc

Quality Biotech  
Development & Cells

## 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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products

temis

metis

eddi





# 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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