

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

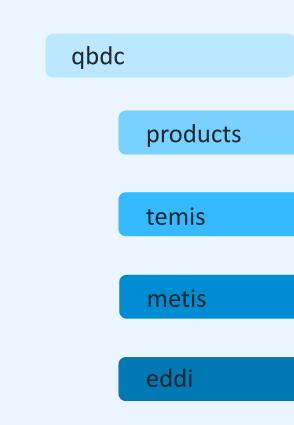
Our services

- Consultancy
- Hands-on work
- Training
- Networking

Our solutions

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





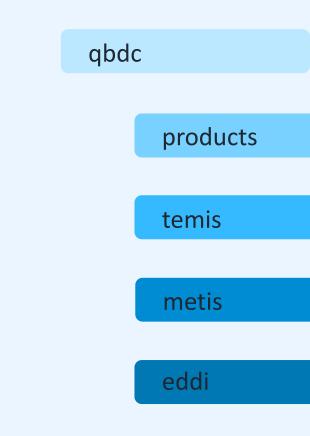
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Consultancy

- 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



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



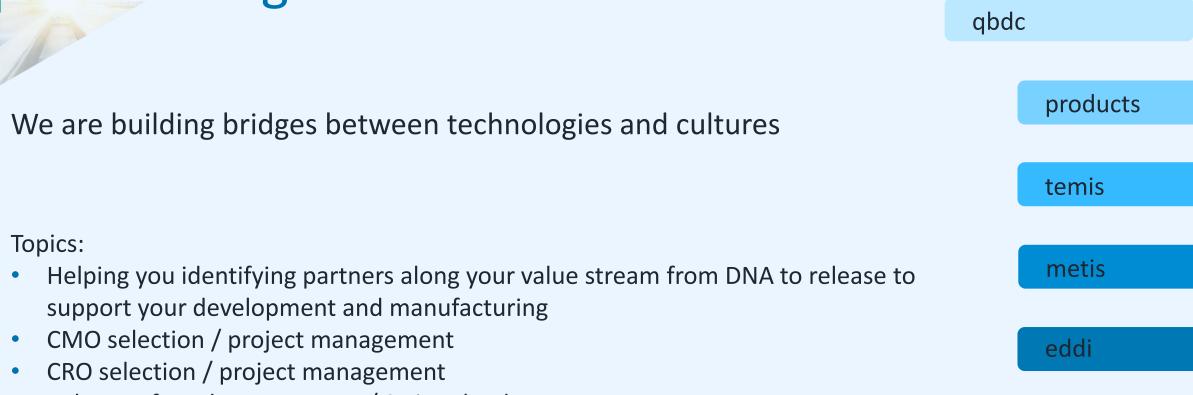
<u>a</u><u>b</u><u></u><i>d<u></u><u>c</u>

Training



- CMC development
- Scientific background ۲
- IMPD / MAA

Networking



• Release of product to Europe / Switzerland





cGMP-compliant document management software:

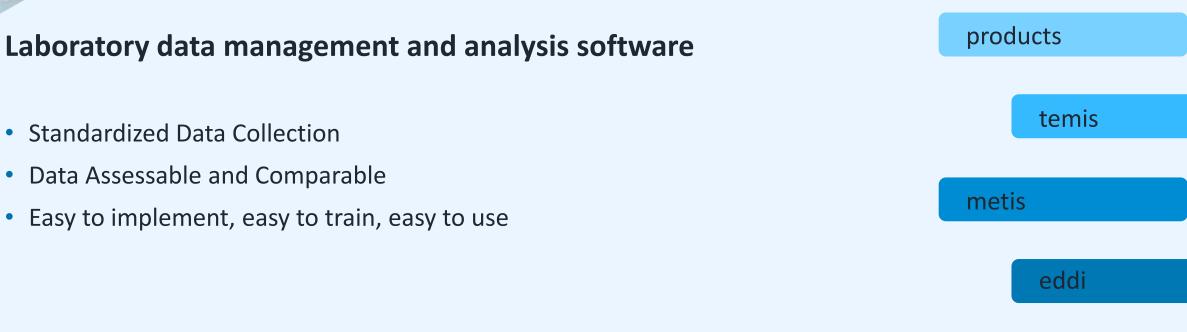
- Accompany documents from preparation to archival
- Fully Digital Work Flows
- Cost effective
- Easy to implement, easy to train, easy to use



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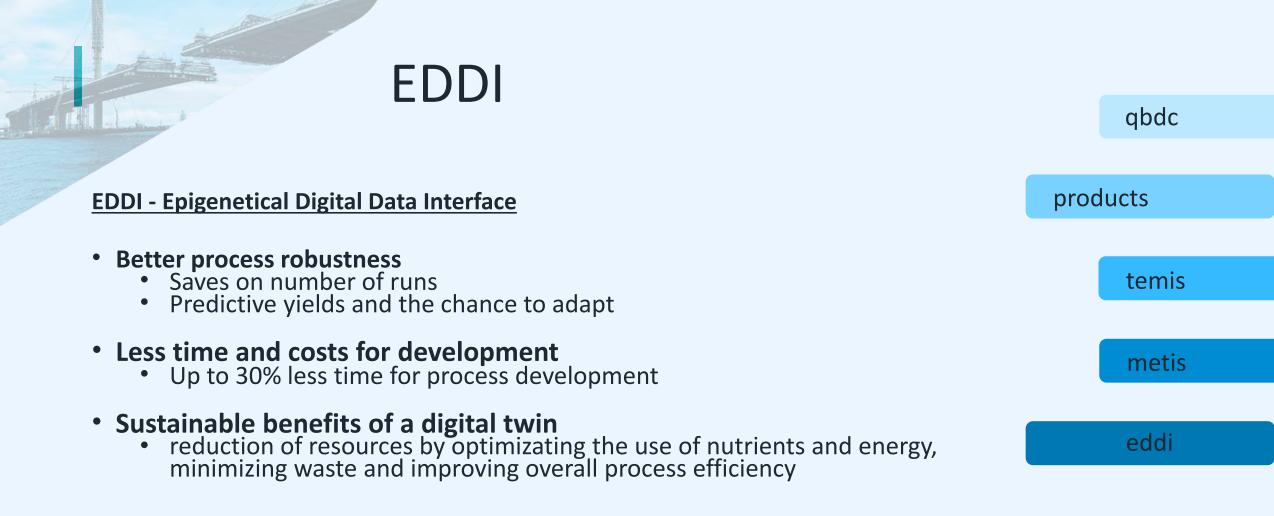
Highly increasing efficiency





Analyse ALL process steps with the same care

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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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products
temis
metis
eddi