quality biotech
DEVELOPMENT & CELLS GMBH

WHO ARE WE

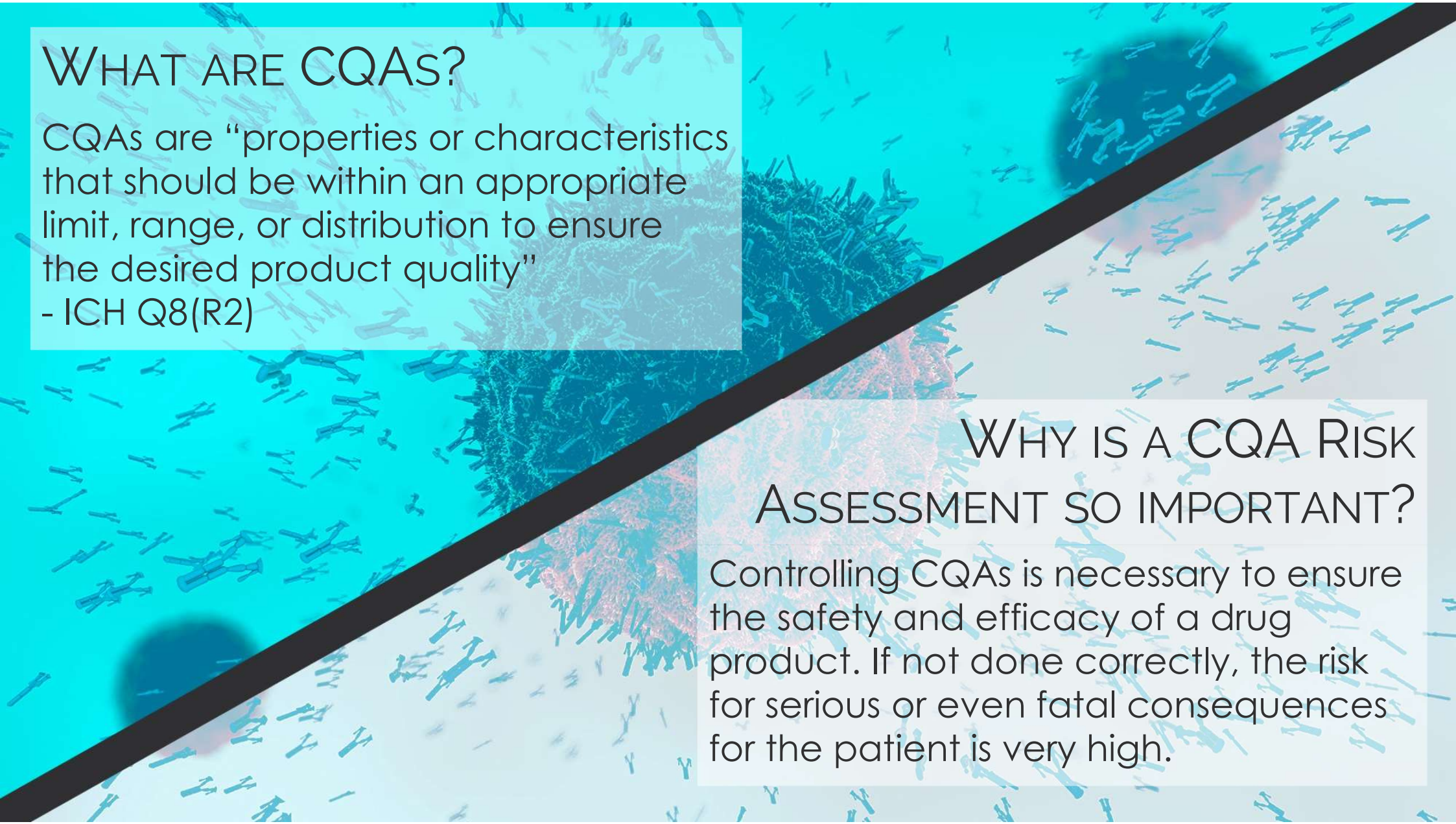
QBDC GmbH is an international consulting company and service provider. QBDC focuses on the quality, development, and production of biosimilars, NBEs, and ATMPs.

WHAT WE OFFER

Whether you seek insight into biopharmaceutical topics, look for services of CDMOs, or even require assistance with a full-scale project development plan, we get your company where you want it to be.

OUR LOCATION

Based in Switzerland, we provide a neutral ground in the center of Europe to our international clients



What are CQAs?

CQAs are "properties or characteristics that should be within an appropriate limit, range, or distribution to ensure the desired product quality"
- ICH Q8(R2)

Why is a CQA Risk Assessment so important?

Controlling CQAs is necessary to ensure the safety and efficacy of a drug product. If not done correctly, the risk for serious or even fatal consequences for the patient is very high.

How to understand & control CQAs

A practical workshop by QBDC GmbH

Goal: Determine the CQAs of your MAb molecule out of 44 quality attributes

Method: Introductory workshop to understand how to work with the QBDC CQA Risk Assessment document efficiently, and self-study

Time: 6h workshop, 2h follow-up consultancy
(self-study of document not included)

Biosimilar Development

Overview of technical challenges
Regulatory requirements

Post translational modifications

USP Perspective
DSP Perspective
Impact on analytical development

Risk Analysis

General explanation
Using risk assessments for CQA determination

CQA Risk Assessment details

Usual critical quality attributes
Standard quality attributes
CQA and batch release