GOOD MANUFACTURING PRACTICE (GMP)

GOOD CLINICAL PRACTICE (GCP)

GOOD LABORATORY PRACTICE (GLP)

Trainees: Jolanda Muurman,
Dr. Marleen Verbeeck,
Martijn Baeten
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<th>Webinar 1</th>
<th>GMP &amp; Basic Principles Manufacturing Process</th>
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<td><strong>Date:</strong> 22 June</td>
<td><strong>14h00 – 16h15</strong></td>
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| **Introduction in GMP (lecture)** | - GMP, a brief introduction  
- The GLP, GCP, GMP landscape  
- The world according to pharma  
- How to implement? Insight, execution/performance and behaviour  
- GMP – Assurance and principles  
- GMP - How do they do it?  
- Pharmaceutical Supply Chain |
| - Basic principles of a (bio)pharmaceutical manufacturing process (lecture) | - Reference to the guidelines  
- Biotech Product characteristics  
- API/ Bulk Drug Substance Manufacturing and Critical Quality Attributes (CQA's)  
- Drug Product Manufacturing and Critical Quality Attributes (CQA's)  
- General Manufacturing requirements  
- Back up: cell line management and impurities  
- Part II: GMP for Active Product Ingredients  
- Part III: Additional Documents |

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<th>Webinar 2</th>
<th>Quality Systems &amp; Working at a Manufacturing Plant</th>
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<td><strong>Date:</strong> 23 June</td>
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| - The main quality systems (lecture) | - Deviations &OOS  
- CAPA  
- Change Control |
| - Investigating a Deviation (workshop) | - Cases for investigation:  
  - Equipment breakdown in grade A  
  - Filter test failure in an aseptic manufacturing process  
  - Too much antifoam added during cell culturing |
| - Working in a pharmaceutical plant - departmental responsibilities | - Producing at manufacturing department  
- Maintenance by the Facilities department  
- Testing at the QC department  
- Tasks of the QA department and the role of the QP |
| - The Regulatory Affairs department |
## Part 2: GOOD CLINICAL PRACTICE (GCP) Agenda

**WEBINAR 3**  
**DRUG DEVELOPMENT & CLINICAL TRIALS**

**Date: 24 June**  
**10h00 – 12h15**

- Drug Development in Steps:  
  - Investigational Medicinal Products  
  - Non-Clinical Research  
  - Clinical Research in Steps: Different Trial Types, Timeline & Cost  
- Rules for Clinical Research:  
  - Why Rules? Declaration of Helsinki and GCP  
  - Legislative Binding Rules for Clinical Research  
- Linking GMP, GCP, GDP  
  - Investigational and Auxiliary Medicinal Products

**WEBINAR 4**  
**CLINICAL TRIALS: STEAKHOLDERS, PRINCIPLES, DOCUMENTS, CYCLE**

**Date: 25 June**  
**10h00 – 12h15**

- Stakeholders of Clinical Trials  
  - Sponsor, Investigator, Ethics Committee, Regulatory Authority  
- Principles and Documents of Clinical Trials  
  - Clinical Trial Principles  
- Life Cycle of Clinical Trials  
  - Trial Design, Trial Approval / Authorisation, Selection of Investigators & Study Subjects, Collecting Data, Trial Results, Milestones

**WEBINAR 5**  
**RESPONSIBILITIES**

**Date: 30 June**  
**10h00 – 12h15**

- Sponsor’s Responsibilities in Clinical Trials  
  - GCP – GMP – GDP responsibilities  
- Investigator’s Responsibilities in Clinical Trials  
- Investigational Products’ Documents

**WEBINAR 6**  
**QUALITY ASSURANCE & POSITIONS IN CLINICAL RESEARCH**

**Date: 01 July**  
**10h00 – 12h15**

- Quality Assurance & Audit/Inspection Findings  
  - Quality Assurance & difference between audits & inspections?  
  - Is it a serious? Common findings & how to avoid them  
  - Difference between Regular Medical Care & Clinical Trials  
- Sponsor’s Positions in Clinical Research in Clinical operations, Data management, Regulatory Departments, etc.
### Part 3: GOOD LABORATORY PRACTICE (GLP) Agenda (preliminary)

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<th>Webinar 7</th>
<th>History &amp; Principles of GLP in Clinical Research</th>
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<td><strong>10h00 – 12h15</strong></td>
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<td><strong>Webinar 8</strong></td>
<td>History &amp; Principles of GLP</td>
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<td><strong>Date:</strong> 14 July</td>
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<td><strong>10h00 – 12h15</strong></td>
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**GOOD MANUFACTURING PRACTICE (GMP)**

**Trainer: Jolanda Muurman**

With a degree in Bioprocess engineering and in Management, Jolanda Muurman works in the (bio)pharmaceutical industry since 2000. She started her career in the quality unit of one of the top 10 pharmaceutical companies. Her first steps were in the area of pharmaceutical packaging and the critical aspects of printed packaging materials. From there she moved on to parenteral and biotech product. For five years she has worked for a CMO in the field of Bulk Drug Substance manufacturing and Fill Finish of Investigational Medicinal Products. Combined with a manufacturing background and thorough understanding of GMP and Quality Assurance in biopharmaceutical product development, she has worked as a Qualified Person for IMP’s in the different stages 1, 2 and 3 of clinical product development. She speaks English and Dutch.

Her passions are GMP-trainings:
- GMP trainings
- Biotech manufacturing processes
- Risk Based Product development
- Validation

But she also works in the field of training development and design. She is providing standardized training but also tailor-made sessions adapted to the specific needs of the client and the company.
GOOD CLINICAL PRACTICE (GCP)
Trainer / Marleen Verbeeck

Marleen Verbeeck has a PhD in molecular biology and is a clinical research professional since 1995. After her academic career in scientific research at universities of Leuven, Utrecht, New York and Maastricht, and the European Commission, she gained solid grounding in clinical research, first as a clinical research associate, later as a medical writer and trainer at clinical research organisations. Since 2004 she enjoys developing and lecturing courses at the European Centre for Clinical Research Training (ECCRT). She trains staff from multinationals and small businesses of the pharmaceutical and medical device industry, of universities, as well as non-profit research organisations, across Europe, the United States of America and the Middle East. She is specialised in clinical operations and regulatory requirements of clinical research. As a trainer her expertise is “trial legislation and clinical operations”:

- Good Clinical Practice
- Legal Requirements in Clinical Research in Pharmaceutical and Medical Devices industry in Belgium/ in Europe/ and in the USA
- Preparing for Audits/ Inspections
- Clinical Research Trainings for Administrators/Assistants
- Clinical Research Trainings for Clinical Trial Monitors (juniors and seniors)
- Clinical Research Trainings for Investigational Site Team
- Clinical Research Trainings for Investigators

GOOD LABORATORY PRACTICE (GLP)
Trainer: Martijn Baeten

Graduated in 2004 as master in bio-engineering at the university of Brussels. Martijn Baeten started as scientific research associate at Beta-Cell N.V., a company involved in xenotransplantation for diabetes in 2005. In 2008 he started working as a scientist on cancer immunology at the University of Brussels. He was also the head of the core facility flow cytometry at the University of Brussels. From 2011 he started working as a GLP inspector at the Institute of Public Health (called Sciensano since 2018). He is also an internal auditor for ISO 17025 & 15189 and ISO 9001 for Sciensano. At the moment, he is also involved in the implementation of an ISO 27001 quality system. As member of the Belgium GLP monitorate, he was involved in the drafting of the new OECD document on computerised system. He is also an active member of the OECD GLP working group and steering group for OECD training courses for GLP inspectors. Since September 2019, he coordinates the Belgian GLP monitorate. As member of the steering group for OECD training courses, he presented several topics during the OECD training courses for GLP inspectors in 2013 (Tokyo), 2015 (Hyderabad), 2017 (Krakow) and 2019 (Cape Town). Topics covered included “Use of computerized systems in GLP”, “Equipment, material and reagents”, “Roles and responsibilities”, “QA program”. As trainer, he also prepared and gave several workshops on IT validation in GLP, Conducting study audits, Study Reconstruction & Data Integrity…