

Upstream Process Scale-Up and Validation

4-week online academy | Starts 5 October



**BioProcess
International
Academy**

Your Course Leader - Dr. Margit Holzer

Margit is a specialist in process, product and analytical methods development for preclinical and clinical production phases as well as for commercial supply.

She began her career working at Boehringer Ingelheim, eventually establishing and becoming the head of the new division of manufacturing sciences. She moved on to become the Quality Director and later on the Technology, R&D and Innovation Director for NOVASEP in France, before setting up her own consultancy.

She now assists clients in the evaluation, optimization and development of processes, analytics and technologies including innovative ones for Up & Downstream processing and Formulation. She has 25 years' of experience in the industry and has worked on more than 50 different products.



Agenda

Module 1: Upstream equipment

- Principal format examples
 - > Well plates
 - > Shake flasks
 - > Wave bags
 - > Roller bottles
 - > Stirred bioreactors
 - > Stirred fermenters
 - > Fixed bed
- Importance of design and instrumentation (stirrer, gassing, pH control, duration)
- Use of small scale models in development
- Explore the types of bioreactors and fermenters available, their advantages and limitations:
 - > Stainless steel
 - > Single use

Agenda

Module 2: Process characterisation

- Definition of CPPs
- Range studies (e.g. split ratios, gassing, feeding, pH control, temperature)

Module 3: Integrating with downstream processing

- Understanding the needs of the DSP
- Collaboration between USP and DSP

Module 4: Scale Up and process transfer considerations

- Process descriptions
- Parameters and ranges to monitor and control
- Equipment & utility description, characterisation requirements

Agenda

Module 5: Quality considerations

- Quality by Design
- Experimental design
- Knowledge management
- Risk management

Module 6: Control strategy

- Overview
- Requirements
- Specifications for specific material
- PAT
- Sensors and measurements
- Control loops
- Control hierarchy
- Data analyses

Agenda

Module 7: Process performance validation

- Studies to be included
- Protocol and report requirements
- Scale and number of batches
- Continuous processing – how to address implementation challenges for industry

For information or to book a course
please contact our Training Consultants

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