# The Scale-Up of Chemical Processes

SCIENTIFIC UPDATE
We've got chemistry

## *Virtual Conference | October 19-21, 2020*

## PROGRAMME

### Monday October 19, 2020

From 2.00pm (UK); 3.00pm (Central Europe); 09.00 am (EDT); 6.00 am (PDT) each day

***Session Chair:*** ***Dr John Studley,*** *Scientific Update Ltd*

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| 2.00pm | **Opening Remarks – Dr John Studley** |
| 2.05pm | **Dr Alessandro Agosti,** Olon Spa, Italy<br>*Continuous Safety Improvements to Avoid Runaway Reactions: The Case of a Chloro-Thiadiazole Intermediate Synthesis toward Timolol* |
| 2.50pm | **Dr Mark James Ford,** Bayer, Germany<br>*Agrochemical Process Research: The Search for the Holistic Solution* |
| 3.35pm | Interval |
| 4.00pm | **Dr Ronald Carrasquillo, Bristol Myers Squibb**, USA<br>*PAT Enabled Development of a Semi-Continuous Drug Substance Manufacturing Process* |
| 4.45pm | **Dr Alison Campbell Brewer,** Eli Lilly, USA<br>*Design, Development and Scale-Up of a Homogeneous Chan-Lam Coupling* |
| 5.30pm | ***End of Virtual Conference Day 1*** |

### Tuesday October 20, 2020

From 2.00pm (UK); 3.00pm (Central Europe); 9.00 am (EDT); 6.00 am (PDT) each day

***Session Chair:*** ***Dr Will Watson,*** *Scientific Update Ltd*

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| 2.00pm | **Opening Remarks –** |
| 2.05pm | **Dr Leo Hardegger,** Novartis, Switzerland<br>*Using Phenylalanine Ammonia Lyases in the Manufacture of EMA401* |
| 2.50pm | **Dr John Snoonian,** Sunovion, USA<br>*Development and Pilot Manufacture of an API Using Continuous Manufacture of a Key Intermediate* |
| 3.35pm | Interval |
| 4.00pm | **Keith Mattern,** Merck, USA<br>*Data Rich Experimentation Across Scale: Leveraging PAT and Reactor Automation for Robust Process Design* |
| 4.45pm | **Dr Donald J. Knoechel**, Fauske & Associates, USA<br>*Process Safety Scale-Up Aspects of a Nitric Acid-Catalyzed Epichlorohydrin Hydrolysis Reaction* |
| 5.30pm | ***End of Virtual Conference Day 2*** |

# The Scale-Up of Chemical Processes

## Wednesday October 21st, 2020

From 2.00pm (UK); 3.00pm (Central Europe); 9.00 am (EDT); 6.00 am (PDT)

**2.00 – 2.45pm** **Hosted Discussion Sessions – Session 1 – choose 1 from the following 3 rooms:**

**Room 1 | Mettler Toledo**

*Data-rich Experimentation to Accelerate Development Time*

Chemical process development and scale-up from the lab to a commercial scale presents challenges including engineering, safety, and economics. Join us for a panel discussion and hear about real-life scale-up challenges from 4 industry experts. Learn how the their application of PAT for data-rich experimentation (DRE) improved process understanding, facilitating optimization and scale-up to commercial scale.

**Room 2 | Scale Up Systems**

*Mixing workshop: From lab to plant, scale-up tips and methodologies*

Mixing can affect all processes which have competing rate processes, like parallel consecutive reactions or crystallizations. In this session our experts will discuss how to understand the importance of mixing on scale-up performance for your key processes responses. We will share a protocol to efficiently identify mixing issues that can affect process responses on scale, with some examples of how this has been used in pharmaceutical and fine chemical companies.
We will then show how typical mixing criteria can be efficiently predicted using simulation tools and how those scale-dependent parameters can be layered on top of scale-independent reaction to kinetics to predict critical quality attributes such as yield and selectivity for right-first-time scale-up.

**Room 3 | Concept Life Sciences**

*Candidate nomination: What's next? Managing risk and return on investment in early development.*

Our experts will begin with a short presentation on a real life case study for a first GMP campaign, followed by a panel discussion on key questions around strategies in early development to maximise return on investment and minimise risk. The discussion will touch on the topics and challenges below:

1. The data gathered in discovery must be verified and solidified in early development. Quality data allows confidence to fail fast or proceed and invest with confidence. Which areas do you focus on first to ensure your firm foundation?
2. A candidate molecule (usually!) comes with a synthetic route. If it is possible to deliver sufficient material for your next set of development work, what factors would you consider before investing in route design?
3. The “developability” of a compound is often influenced by the solid form and ultimately the formulation selected. How can we set ourselves up for success in early development? What are the key challenges we will have to overcome in solid form selection, salt form selection and pre-formulation activities? What can guide us where to start?

**3.00 – 3.45 pm Hosted Discussion Sessions – Session 2 – choose 1 from the following 3 rooms**

**Room 4** | **Phosphonics**

*Optimising scavenging processes for more sustainable and cost effective chemical processes*

Catalysis is ubiquitous in the chemical industry and is a key pillar of green chemistry. We will discuss with the attendees their use of catalysis, showing how scavenging can be a more cost effective solution than most people imagine. We will share our approach to optimising cost effective scavenging processes and share case studies on the removal of metal impurities to meet the ICH guidelines as well as the recovery of value from waste streams for more cost effective and sustainable catalytic processes.

**Room 5** | **Kaneka**

*Enabling Manufacturing with Enzymes and Flow Chemistry - Robust Route Development for Successful Scale-Up*

With 50 years experience in researching, engineering, and scaling up commercial scale biosynthesis, this discussion group will focus on typical issues and questions associated with exploring biocatalysis as a tool for small molecule synthesis. This includes screening approaches, barrier to entry, scale capabilities, and using 'off the shelf' vs a custom enzyme approach.

We will also cover the research and scale-up of continuous manufacturing methods, including the ability to scale enzymatic processes into a continuous process through immobilization.

Real lab and commercial scale case studies will be provided as a means for discussion.

**Room 6 | Mettler Toledo**

*Interfacing PAT with Reactors, and Integration and Management of Data*

With all the challenges chemical process development and scale-up from the lab to a commercial scale presents, we are often asked very practical questions – "How complicated is it to interface a PAT probe with a reactor?", or "How does one manage and use the dense data that is collected?". Join us for a live discussion to review frequently asked questions about taking the next steps in implementing PAT and data management strategies for scale-up studies and processes.

3.45 pm ***Virtual Conference Ends***

# The Scale-Up of Chemical Processes

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