RSC INTEREST GROUP
PROCESS CHEMISTRY AND TECHNOLOGY
https://www.procchem.group

Newsletter

December, 2020

Improving Our World by Advancing the Application of Chemistry at Scale

The chemical sciences are vital for the wellbeing of our world. The know-how to efficiently and safely perform chemistry at industrial scale is a critical element – this is the focus of this interest group.

UPDATES ON PCTG'S ACTIVITIES

The PCTG committee has been actively planning various virtual activities in response to the lockdown.

ProcTank

The committee has been developing a repository of information related to process chemistry. This is part of the Group's mission to provide a means to disseminate knowledge and best practice in the field of applied process chemistry.

PCTG has recruited a placement student for developing ProcTank knowledge repository.

If you would like to help with ProcTank's development, or you have materials and know-how that you are able to share, please contact us for further details.

IN THIS NEWSLETTER

RECENT EVENTS AND WEBINARS

How to Ensure Quality by Design – A Practical online Workshop

28th, 30th Sep and 2nd Oct 2020

This event included hands-on exercises, data analytics tools and virtual process simulators. Our expert speakers used industry case studies to demonstrate key tools like Design of Experiments. ***Read more in the article below.***

Kinetic Modeling: An Essential Practice in Chemical Process Development

by Dan Hallow, Principal Consultant at Scale-up Systems

29th Sep, 2020

Molecules to medicines: informatics approach to pharmaceutical development and manufacturing

by Andrew Maloney, Research and Applications Scientist at CCDC, Cambridge

27th October 2020

For more information on these past events, please visit https://www.procchem.group.

CALL FOR TOPICS AND SPEAKERS FOR THE 2021 WEBINAR SERIES

The PCTG committee is currently planning to launch a new monthly webinar series for 2021 to help us with our goals of bridging the gap between process chemistry and technology, aiding innovation, and raising awareness of current issues in the field.

We would like your help:

- What webinars would you like to see?
- Have you seen a great presentation somewhere else that would be compelling and relevant for our membership?
- What are the hot topics and current challenges in process chemistry we should be talking about?
- Do you have an innovation, a discovery or a technology that you would like to tell the community about?
- Could you help us to reflect the diversity of organisations, people and careers in process chemistry and technology by telling your story?

Contact us with your ideas via the **PCTG website**.

UPCOMING EVENTS

Annual symposium on Innovations in process chemistry and technology

Postponed to November 2021.

CPACT webinars

CPACT is offering the following exciting webinar programme of interest to PCTG members:

- **Food Analysis by Raman Spectroscopy** 10 Dec 2020.
- **Metabolic Modelling in Bioprocessing: How to use genome scale metabolic models to gain process understanding** 27 Jan 2021.
- **Process Analytical Techniques for End-Quality Variance Reduction** 28 Jan 2021.
- **In-line Chromatography**, 11 Feb 2021.

IChemE Webinars of interest to our members

- **Catalysis for Production of Clean Energy,** 23 Nov 2020, URL.
- **Webinar: Commercialising Industrial Biotechnology**, URL.
- **Webinar: How 3D Printing of Reactors can help Chemicals Engineers with Process Intensification**, 10 Dec 2020, URL.

For more information on future events, please visit https://www.procchem.group.

NEW COMMITTEE MEMBERS

The PCTG committee welcomes the following new members, who further strengthen the committee with their rich experience in process chemistry and technology.

Fraser Kerr FRSC, Founder and Owner of Astute Pharma Associates Ltd.
Fraser is a chemist by training with 28 years of experience in the Pharmaceutical Industry in a variety of roles within Process Research & Development at AstraZeneca (AZ), both in the UK and abroad. He focuses on helping SMEs within UK and Europe to scale up processes and businesses. Fraser is part of the Mentoring Programme for Chemistry & Chemical Engineering students at Lancaster and Manchester Metropolitan Universities. In addition, he is a Business Coach for the European Commission Horizon 2020 initiative.

Giuseppe Fiorello CChem, IPI Global Ltd
Giuseppe focuses on the H&S and environmental sector with a product for safely handling chemical liquids. He is responsible for the markets in Spain, Portugal, Italy, Netherlands, Denmark and Finland dealing with the biggest Chemical Companies such as Brenntag, Lanxess, DOW, Covestro, BASF, etc. Giuseppe also liaises with DEFRA, the ECHA and the EU Commission to raise awareness about new regulations, directives and the latest EU Circular economy and UN SDG developments

Alan Steven, CatSci Ltd
Alan currently holds a scientific leadership role within CatSci, a Cardiff-based innovation development organisation. His role involves collaborating with agrochemical firms and equipment vendors, and advisory board input into CDTs offering training in enhanced chemical development methods and the UK Catalysis Hub. Alan is passionate about the design of inherently green process development solutions, which has yielded 36 articles of interest to process chemists and engineers in *Org. Process Res. Dev*., ongoing leadership of the associated ACS GCI Pharmaceutical Roundtable subteam, and many well-read postings on LinkedIn and Twitter. He is one of the founders of LabLinks, a platform for linking chemical development knowledge. Alan also has expertise in QbD and participates in the ISPE lifecycle control strategy community of practice.

Andrew Byrne CChem & EurChem, APC Ltd.
Andrew is a senior research scientist at APC Ltd in Dublin, Ireland. He has a strong background in industrial and pharmaceutical chemistry with expertise on Process Analytical Technologies and process development. Andrew is keen to promote careers in process chemistry.

Mariyam Bi Placement student, PCTG and xSeriCon.
Mariyam studies chemical engineering at The University of Sheffield and now is on her placement year with xSeriCon and PCTG, focusing mainly on the development of ProcTank, the PCTG's very own knowledge repository. She is currently enjoying learning about functional safety concepts under the supervision of Peter Clarke at xSeriCon and populating the ProcTank repository. She aims to gain industrial experience in the chemical engineering industry with focus on sustainability, renewable energy and process safety. She is passionate about a career in research and her highest ambition is becoming an astronaut.

ACCELERATING R&D: HOW TO ENSURE QUALITY BY DESIGN PCTG WORKSHOP

by Dr Phil Kay CChem MRSC (JMP)

It typically takes more than a decade to get a new pharmaceutical product to market. At the time of writing, the first vaccine has just been approved for use in the UK having only been created earlier this same year. How has this acceleration been possible? And can other industries learn from this to help them reduce the time it takes to get their innovations to customers?

Photo by Artem Podrez from Pexels

Until recently I expect most people outside of the industry didn't care much about pharmaceutical development timelines. Now news on the rapid delivery of innovative Covid-19 vaccines and treatments regularly makes the headlines. In fact, such accelerations of drug R&D are not without precedent. One of the advances that has enabled this is the implementation of Quality by Design (QbD) methods, which allow key parts of these projects to be completed in reduced time without increasing risk to patient safety.

The slow process of running clinical trials normally dictates the timeline in pharmaceutical development. Multiple phases involving thousands of patients need to be completed to demonstrate efficacy and safety before a submission can be made to regulators for approval. But in examples from newer classes of therapeutics for rare diseases the benefits to patients can be so dramatic that large and lengthy trials are not needed. Getting innovative therapies from discovery to delivery in minimum time becomes a moral imperative. What else happens when these clinical trials are shortened from years to months?

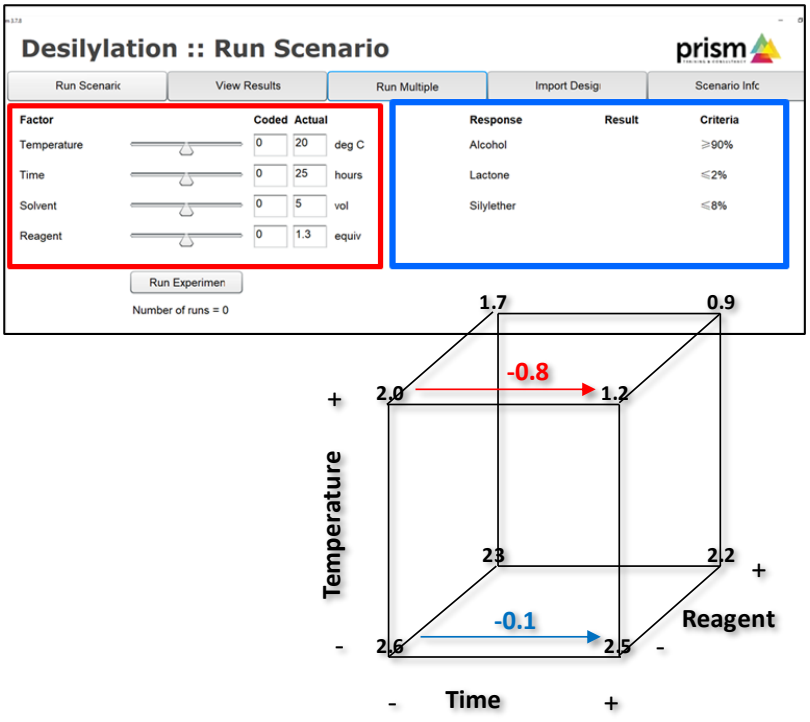
In these cases, you also need to accelerate the less glamorous work of development that is usually carried out in the background with less fanfare. These tasks are just as important in ensuring that the drug or therapy can be delivered to all those that need it while ensuring efficacy and safety. You need to work out how to make the product with maximum efficiency and demonstrate to regulators that you understand how to control the process to ensure consistent quality. You also need to develop assays and characterisation methods for quality control. And you will need to understand the shelf-life under different conditions. (Who knew that extreme cold storage would be such a hot topic this year?)

QbD has been a key tool for shortening the completion time for these activities. Big improvements in R&D efficiency are gained through a strategic focus on risk, understanding and control using a combination of expert and data-driven analysis. These methods have helped many pharmaceutical organisations to consistently deliver high quality products in the face of complex technologies, risk factors and many sources of variation. And to do all this faster.

Surely these methods would be of benefit in other industries where the need for speed in R&D is important and where regularly getting your latest products to the market without problems or delay can make the difference between success and failure of the enterprise. It seems these approaches should be just as valuable in industries such as consumer packaged goods, biotechnology, speciality chemicals and advanced materials. How have pharmaceutical scientists managed to keep this secret to themselves?

In fact, "Quality By Design" was not invented in the world of medical products. The term was coined by Joseph Juran, who drew on his early experiences working as an electrical engineer at Western Electric to become an influential writer on quality improvement. Juran was not only concerned with his own industry, or even just engineering and manufacturing companies. As a management consultant, he worked with a broad range of industries and organisations including Xerox, Phillips, Volkswagen and the United States Navy. It was only after his retirement that the pharma-centric QbD that we now know became popular when medicines regulators began to advocate for it. Despite attempts to re-brand the methods and align with industry trends ("Design for Six Sigma"), QbD has never really taken off to the same extent in process industries more broadly.

Hopefully you can now understand why 'increasing the uptake of QbD methodologies in all industries and chemistry types' is one of the current challenge statements of the Process Chemistry and Technology Group. In 2019 we curated a virtual seminar hosted by Chemistry World on the subject with presentations from industry and academia experts. If you want to learn more about QbD then the recording of this event would be a good start: https://www.chemistryworld.com/webinars/how-to-ensure-quality-by-design/3010849.article



As a follow-up we held an online workshop, "How to Ensure Quality By Design", at the end of September 2020. This training was offered at a heavily discounted rate thanks to sponsorship from the PCTG and JMP® Statistical Discovery™ Software. Attendees from pharmaceutical development, agrichemicals, academic research institutes and the biotechnology industry engaged with hands-on exercises, data analytics tools and virtual process simulators. Our expert speakers, Martin Owen (Insight by Design, ex-GSK) and Walkiria Schlindwein (De Montfort University Leicester School of Pharmacy), used industry case studies to demonstrate keys tools like Design of Experiments. Feedback from the attendees was overwhelmingly positive.

You can watch a short highlights video here: https://www.linkedin.com/posts/drphilkay_qbd-chemistry-academia-activity-6732198424248115200-L_7b

ABOUT THE PROCESS CHEMISTRY AND TECHNOLOGY GROUP

The vision of this group is to be a place where process chemistry and process technology join together and to bridge the gap, aid innovation and raise awareness of current issues in the field. The PCTG, comprising some 800 members across multiple sectors, is led by an enthusiastic committee of professionals, all of whom are active in this field.

The PCTG, through its membership and networks, are leading the way to challenge the UK industry to think differently about how to approach the world's future process chemistry and technology challenges.

By engaging with the PCTG you can:

- Promote and contribute to the advancement of industrial-scale process chemistry and technology
- Develop your skills and understanding by learning from experts in the field
- Boost your career, raise your profile, and build your network of like-minded chemical scientists from industry and academia

New members are always welcome, to help us drive our exciting programme of activities and projects. The Committee meets 3 times per year in London. On the other 9 months of the year, the Committee meets by teleconference.

THE COMMITTEE

Chair: Dr Carl Steele *CChem FRSC* (Orano Projects Limited)
Treasurer: Dr Mark Hughes *MRSC* (ex-GSK)
Secretary: Dr Phil Kay *CChem MRSC* (JMP)
Committee Members:
Mariyam Bi, Placement student.
Andrew Byrne *CChem EurChem* (APC Ltd.),
Dr Mukund Chorghade *CChem FRSC* (THINQ Pharma),
Dr Peter Clarke *CChem MRSC* (xSeriCon)
Dr Bethan Coulson *MRSC* (Johnson Matthey Fuel Cells),
Giuseppe Fiorello *CChem* (IPI Global Ltd.),
Dr Charles Gordon (Scale-up Systems),
Richard Hart *CChem CSci FRSC* (AstraZeneca),
Dr. Fraser Kerr *FRSC* (Astute Pharma Associates Ltd.),
Professor David Littlejohn *FRSC FRSE* (University of Strathclyde),
Professor Siddharth Patwardhan *CChem FRSC* (University of Sheffield).
Dr Alan Steven *CChem MRSC* (CatSci Ltd.)

WAYS TO CONTACT PCTG

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