JPAG
JOINT PHARMACEUTICAL ANALYSIS GROUP

ensuring knowledge, enhancing quality

A 'not-for-profit' organisation,
*run **for** pharmaceutical analysts **by** pharmaceutical analysts*

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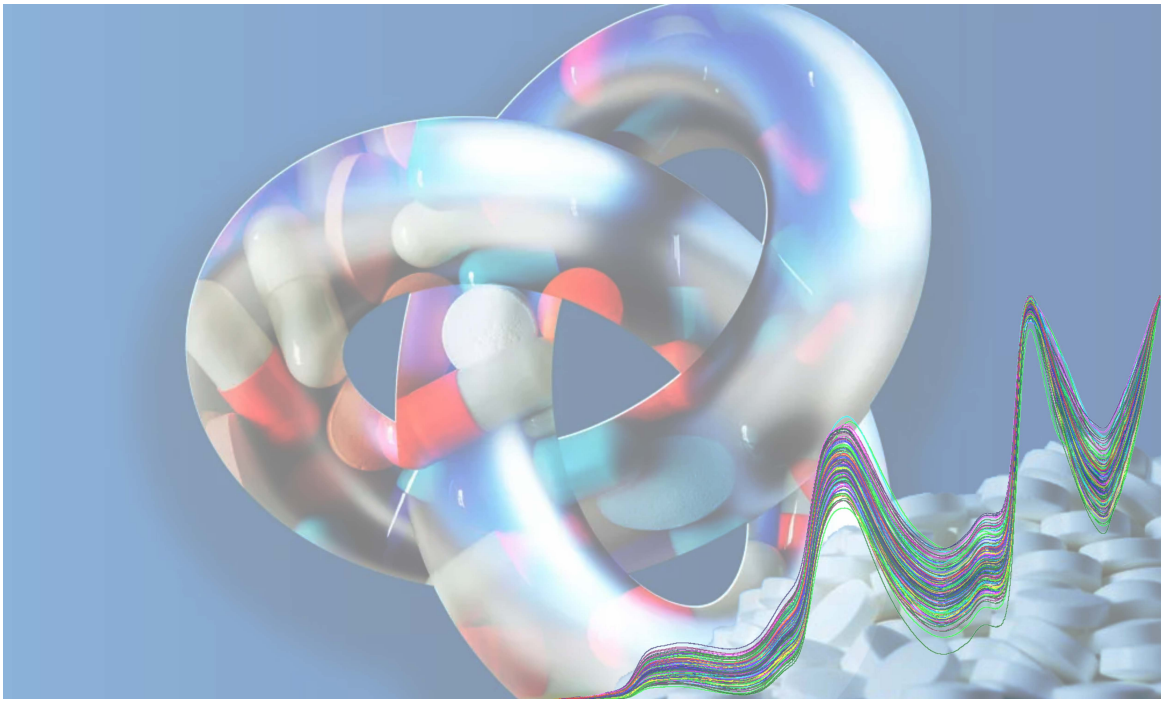
JPAG SYMPOSIUM:

Analytical Strategy to support Continuous Manufacturing



Thursday 26 September 2024
9:00 AM - 5:00 PM

Royal Society of Chemistry, Burlington House, Piccadilly, London, W1J 0BA

ROYAL PHARMACEUTICAL SOCIETY

ROYAL SOCIETY OF CHEMISTRY

https://www.linkedin.com/groups/3796797

events@jpag.org

https://www.jpag.org/173

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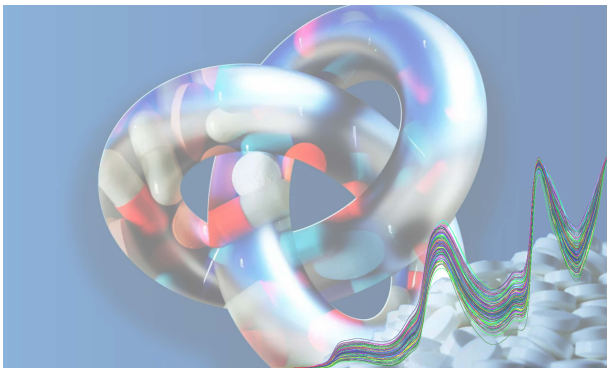
Symposium aims

Continuous manufacturing offers great promise in improving productivity, efficiency and the intrinsic quality of both active pharmaceutical ingredients and formulated products. This symposium will critically examine some of the analytical and quality challenges and opportunities that arise from adopting continuous manufacturing, with examples of how to address them. The symposium also presents an introduction to ICH Q13 and its impact on pharmaceutical analysis.
Leading regulators, industrialists and academics will be sharing their experiences in the development, manufacturing and quality assurance of continuous manufacturing of drug substances and drug products.

Register today at www.jpag.org/cd173



Posters

There will be a display of approved posters that delegates will be able to view and ask questions of the poster's author. If you wish to present your own poster, please see the information on this on the JPAG website at www.jpag.org/info

Exhibitors

If you are a commercial company and would like to exhibit your products, see the JPAG website for details, at www.jpag.org/exhibitors

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Analytical Strategy to support Continuous Manufacturing

Thursday 26 September 2024, Royal Society of Chemistry, London

Purpose of the meeting

Continuous manufacturing offers great promise in improving productivity, efficiency and the intrinsic quality of both active pharmaceutical ingredients and formulated products.
Continuous manufacturing was defined by ICH Q13, the latest version of which completed consultation in 2021, was adopted by CHMP in December 2022 and officially came into effect in the EU in July 2023. The guidance is applicable to continuous manufacturing for new products and the conversion of batch to continuous manufacture for existing products. Changes to the definitions and processes around batch manufacture that carry through into analysis and release of the pharmaceutical product are described with concepts, scientific approaches, and regulatory considerations specific to continuous manufacture of drug substances and drug products.
This symposium will critically examine some of the challenges and opportunities that arise from adopting continuous manufacturing.
Leading regulators, industrialists and academics will be sharing their experiences in the development, manufacturing and quality assurance of continuous manufacturing of drug substances and drug products.

Challenges

What are some of the regulatory challenges?
What are some of the quality challenges, particularly from the perspective of the QP?
What is the right dataset needed to build an appropriate model of a process?
What are some of the PAT applications to be found in a continuous manufacturing process and does this represent a skill gap?
How do you define the specification for a continuous product?

Opportunities

Better understanding of continuous manufacturing and the advancement of PAT will ultimately result in real time release processes. Continuous manufacturing processes have a small footprint so engender more flexible use of space in the factory of the future. Continuous manufacturing can better cope with the peaks/troughs that routinely occur in a supply/demand market.
Analytical Development and QC groups can also benefit from reductions in time and resource for batch analysis as well as real-time understanding of processes and the impact on product quality. Reducing the reliance upon end product testing can also reduce the sampling burden and lead to sustainability improvements through reduced solvent consumption in analytical labs.

Outcomes

You will gain the latest insights into the regulatory, manufacturing and analytical challenges that arise from continuously manufactured products and processes. You will better understand the critical role of chemometrics, PAT and on/at-line analysis for the continuous monitoring and control of these processes. You will be able to network with experts across industry, academia and the regulators.

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Programme

09.00 Coffee and registration

09.50 - 10.00 Welcome and introduction to the morning session
10.00 - 10.50 Keynote Presentation and Introduction to Key Themes (Ian Clegg, AstraZeneca)

10.50 - 11.00 Coffee, exhibition

11.00 - 11.30 Development of a material sparing approach to quantitative in-process spectroscopic powder measurements (Phil Doherty, Expo Process Analytics)
11.30 - 12.00 Working with Large Datasets (Patrick Wray, BMS)

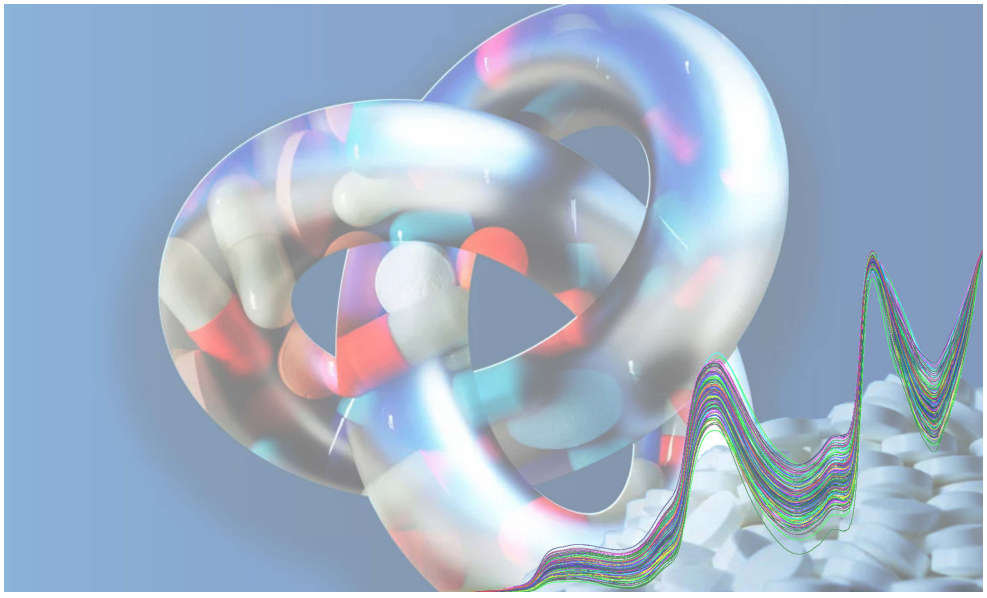
12.00 - 13.00 Lunch, exhibition, posters

13.00 - 13.30 Establishing the LoQ for NIR methodology (Uwe Kirschner, Sentronic)
13.30 - 14.00 On-Line Laser Diffraction and Raman for Polymorphism (Max Besenhard, UCL)
14.00 - 14.30 Machine Learning: A Pathway to Real-Time Release?
(Deborah McElhone, MMIC & John Mack, Applied Materials)

14.30 - 15.00 Coffee, exhibition, posters

15.00 - 15.30 The MACH-1, AstraZeneca Macclesfield's Accelerated Continuous Direct Compression (CDC) Development Hub (Sean Clifford, AstraZeneca)
16.30 - 16.00 A case study through late phase development of a continuously manufactured drug product (Guy Atherton, GSK)

16.00 Close



Delegate information

Registration fees
Full fee £295
Fee for members of JPAG ** £195
Fee for bona fide student in full-time study £45
Fee for retired or unemployed members of JPAG £45
** Details on how members of RPS and RSC can join JPAG are found on the JPAG website.

Registration and payment of registration fees
You can register on-line at www.jpag.org. Please SIGN IN to the site on your first visit before registering for an event; this will ensure that post-event delegate material is fully available to you personally.

Full payment is required at the time of registration. Please pay ON-LINE by credit card (via Paypal). Notification that a registration has been accepted will be confirmed by e-mail to your registered e- mail address. If you have not received notification within five working days please contact JPAG at info@jpag.org. An invoice confirming your registration can be downloaded from the JPAG website. NO OTHER INVOICE WILL BE SUPPLIED. If payment has not been received prior to the event, then entry to the event will be at the discretion of JPAG. Payments may also be made by bank transfer.

Cancellation policy
Meeting registrations once made and accepted by JPAG are liable for payment and are not refundable. However, notified substitutions are permitted at any time prior to the meeting (see below).

JPAG reserves the right to cancel a meeting due to circumstances beyond its control. In this case, JPAG will notify attendees by a message to their registered e-mail address at the earliest reasonable opportunity. It is the responsibility of registered delegates to monitor their e-mail and ensure their registered e-mail address is correct. In the event of cancellation, a full refund of payments will be provided. However JPAG will not be liable, to the extent permitted by law, for any consequential loss or damage arising from the meeting cancellation.

Substitutions
Substitute attendees from the same organisation are accepted at any time with no administration charge. Please notify JPAG in writing via e-mail to events@jpag.org with details of substitute attendees. Substitute attendees must possess an account or register a new account on the JPAG website in order for their registration to be processed.

No refund is payable in relation to any substitution. The full meeting rate will be applied if the substitute attendee is not eligible for a discount and any additional payment is required before a registration can be accepted.

Alterations to the programme
JPAG reserves the right to alter the meeting programme, speakers, date or venue in the event of circumstances beyond its control. For the complete Terms and Conditions, please see the JPAG website.

Other information
Information on the programme, submission of abstracts for Poster presentation, location of the venue and local hotels, and JPAG membership is available on the JPAG website at: www.jpag.org. Other enquiries should be sent to events@jpag.org

The contact details you provide on SIGN IN may be used to inform you about future JPAG, RPS and RSC events, products and services by post, phone or e-mail. However, you can elect not to receive information at any time by updating your profile on the website.