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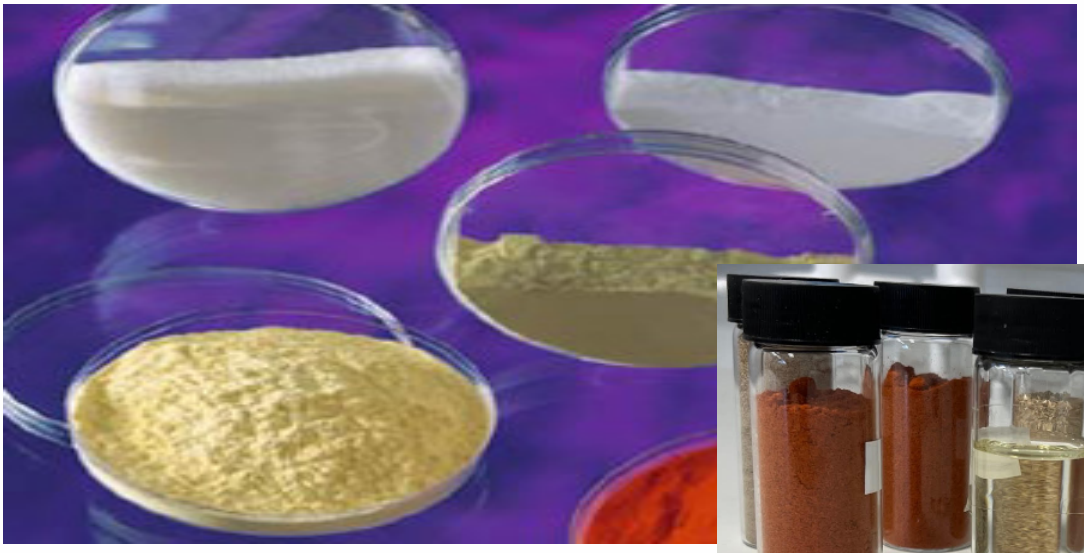
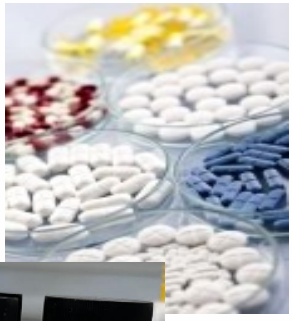




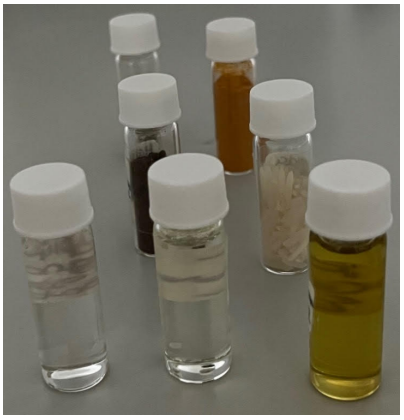
Considering the raw materials:

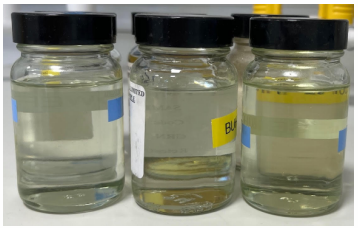
API & Excipients

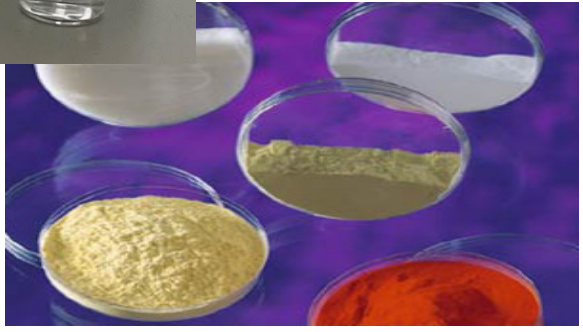
Royal Society of Chemistry

Burlington House, Piccadilly, London W1J 0BA

Thursday 21st March 2024







JPAG
JOINT PHARMACEUTICAL ANALYSIS GROUP

ensuring knowledge, enhancing quality

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

<www.jpag.org>

Considering the raw materials: API & Excipients

Royal Society of Chemistry, Burlington House, Piccadilly, London W1J 0BA
Thursday 21st March 2024

Raw materials, APIs and excipients play an important role in the manufacturing of pharmaceutical products therefore it is important to assess and monitor quality of these materials throughout the product lifecycle. This symposium will present an overview of testing and risk assessment of these pharmaceutical product components throughout the life cycle and could include the key themes below:

- pharmacopoeial monographs for assessing raw materials
- regulatory perspectives (ICH Q7, ICH Q11) covering aspects for small molecules, biologics and ATMPs
- risk assessment of raw materials
- Good Manufacturing Practice
- physical testing including incoming receipt of API & excipients
- method optimisation and development
- stability of APIs
- supply chain impact & resilience
- sustainability

In addition to oral presentations, a panel session is planned for additional debate with our speakers to expand on earlier discussions and include questions not covered elsewhere in the oral programme. We have a shortlist of questions already but can take additional "Questions for the Mar-24 panel" via email to chair@jpag.org or via the guidance on the JPAG information page so we can collate questions on the theme.

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

Interested in this meeting?
Please visit the JPAG website for full details at www.jpag.org

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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.

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.

Programme

09.30 **Registration and Refreshments**

09.55 **Welcome and introduction**

10.00 APIs and excipients: Regulatory expectations & inspection findings
Trevor Watson, MHRA

10.45 Keeping the patient safe: a QP perspective
Richard Smalley, Consultant and QP Assessor

11.25 **Refreshments, Exhibition and Posters**

11.45 History of excipient contamination including proplyene glycol
Andrew Teasdale, AZ

12.20 How can GMP be used to meet current challenges for high quality excipients?
Iain Moore, EXCiPACT

13.00 **Lunch, Exhibition and Posters**

14.00 Speaker Interactive Panel session

14.45 Routine Determination of Nitrite Content to Support Nitrosamine Risk Assessments of Pharmaceutical Samples
Antonia Wierzbicki, Waters

15.15 **Refreshments, Exhibition and Posters**

15.35 New NMR methods for API characterisation and Impurity & Excipient Identification
Ralph W. Adams, Department of Chemistry, University of Manchester

16.10 Physicochemical characterisation of amorphous and crystalline materials using DSC and other techniques
Hisham Al-Obaidi, Reading University

16.45 **Close**

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.

Abstracts

Dr Ralph Adams - Manchester University & RSC NMR group

NMR spectroscopy provides a powerful approach for characterising pure samples of small molecules but can struggle when analytes are complex or are mixed with other species. In this presentation we will discuss the latest toolbox of NMR methods that provide access to the information required for characterisation and quantification of pharmaceuticals in their pure form, when mixed with excipients, or after decomposition. We will introduce pure shift NMR methods, approaches for ultra-selective excitation, how to deal quantitatively with fluorine containing species, and what to do when an NMR spectrum is masked by a huge water signal, giving examples from applications in the pharmaceutical industry where relevant.

Dr Hisham Al-Obaidi - University of Reading School of Pharmacy

Crystal engineering is a broad area of research that includes crystal habit modification, polymorphism, solid dispersions, and salt formation. All these pre-formulation and formulation techniques entail that the drug can be modified using methods such as solvent evaporation or mechanochemical activation. Often, the drug properties can be significantly altered when the crystalline structure is modified such as in the case of amorphous form formation. The outcome of such modifications affects physical properties and can have a dramatic impact on physiological properties, such as bioavailability and absorption. Recent advances in this area of research have shown the potential application of crystal engineering to achieve targeted drug delivery for novel molecules such as anticancer drugs, antimicrobials, and vaccines. Drug delivery applications include various routes, such as oral and pulmonary drug delivery.

Iain Moore - EXCiPACT asbl

The presentation will include the following:

1. Best practice to determine the GMP required of excipient suppliers
2. IPEC-PQG GMP for Excipients and relationship to EXCiPACT GMP
3. How EXCiPACT assures the quality of audits
4. How to use EXCiPACT Certificates and Audit reports
5. Feedback from EXCIPACT stakeholders
6. Q&A

Richard Smalley - Consultant and QP Assessor

As a practicing and experienced QP, Richard will first discuss the legal and routine responsibilities of the QP for active substances and excipients. As a foundation understanding for this key role that directly helps to protect patient safety, he will start with a historical perspective, reviewing legislation and QP duties, before going into several examples of "what can go wrong?" (and cause problems and concerns for the QP during both batch review and Quality System oversight). The biggest risk is active substances (as reflected by 58 pages of GMP Part 2) but excipients (… and other materials) can provide serious risks too, which will be discussed. Finally, he will finish with a discussion of what can come out of the woodwork on a daily basis to challenge the QP before taking questions.

Antonia Wierzbicki - MS Market Development Manager EMEA at Waters

Presence of Nitrites in excipients can pose a risk to the safety of a drug product. Controlling the levels of Nitrite in excipients is a key way to mitigate risk of Nitrosamine formation in a drug product. Here we will describe a strategy to routinely determine nitrite content in excipients that can be applied in pharmaceutical manufacturing.

Speaker biographical details

Dr Ralph Adams - Manchester University & RSC NMR group

Ralph Adams is Head of NMR Spectroscopy in the Department of Chemistry at the University of Manchester, providing NMR characterisation, analysis, training and advice to academic and commercial users and collaborators from around the world. He has active industry and research council funded research programmes in the development of novel techniques in high resolution NMR spectroscopy, and their application to problems in chemistry, biochemistry, and medicine. In many cases this work leads to new pulse sequences and software tools. Ralph heads up a technical team that provides NMR data from 14 instruments for around 200,000 samples per annum to over 400 research scientists. Ralph sits on the committees of several groups including the RSC NMR Discussion Group, the UK Magnetic Resonance Managers Group and the UK Technology Specialists Network.

Dr Hisham Al-Obaidi - University of Reading School of Pharmacy

Hisham Al-Obaidi's research is focused on drug delivery and pharmaceutical sciences which is currently based at the School of Pharmacy, University of Reading, United Kingdom. He has extensive track record in developing solid dispersions for applications in oral and pulmonary drug delivery. His research interests include the assessment of drug-polymer compatibility using thermal analysis methods and the development of particle engineering methods for novel applications such as lung infections and cancer.

Iain Moore - EXCiPACT asbl

Dr Iain Moore has recently retired after working for 36 years with the speciality chemical manufacturer, Croda International plc. After completing his doctorate studies in organometallic chemistry, he joined BP Chemicals and then Croda in 1987. He has acted at the technical – customer interface, led a team of chemists in the development of Croda's products before holding various QA roles since 1995. This includes implementing Excipient and API GMP systems at two manufacturing sites, including two successful MHRA inspections. His final role was as Global Head of Quality Assurance. He has also contributed to the publication of European and US National Standards. He is one of the co-authors of the IPEC-PQG GMP Guide for Pharmaceutical Excipients and the EFfCI GMP Guide and standard for Cosmetic Ingredients. He has been President of EXCiPACT asbl for two terms and is now the Senior Advisor for EXCiPACT asbl. Iain Moore is a member of the Royal Society of Chemistry and The Chartered Institute of Quality.

Richard Smalley - Consultant and QP Assessor

Richard is a Fellow of the Royal Society of Chemistry, has an MSc in Pharmaceutical Quality and GMP, has been a QP for over 20 years, a QP Assessor for 10 years and is entering his 40th year in the pharmaceutical industry. Having worked supporting all dosage forms in medium and large pharmaceutical companies he has also gained direct manufacturing experience in excipients and active substances. He became a consultant and contract QP 9 years ago specialising in aseptically manufactured products and IMPs (including several gene therapy products) but as a highly experienced and respected auditor, he continues to visit global API sites and has completed in excess of 200 API or excipients audits. Richard lives with his wife Jackie in Derbyshire, has 4 children, 2 granddaughters and 2 Basset hounds.

Speaker biographical details

Dr Andrew Teasdale - AstraZeneca
Andrew Teasdale PhD has over 20 years of experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. In his current role he chairs AstraZeneca's Impurity Advisory Group. Dr Teasdale has published a number of papers relating to elemental impurities and other impurity related matters and has been a speaker at many international conferences. Dr Teasdale has also led a number of industry expert groups; these include both safety and quality groups within Pharmaceutical Research and Manufacturers of America (PhRMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Product Quality Research.

Trevor Watson - MHRA
Trevor joined the MHRA Inspectorate in 2014 and is currently a Lead Senior GMDP Inspector. As well as inspecting sites in the UK and overseas, he is the GMP technical lead for importation and for medicinal gases, and he liaises with the Joint Professional Bodies on QP matters. He previously worked in the pharmaceutical industry for over 25 years in a variety of QC and QA roles and is also eligible to be named as a Qualified Person under the permanent provisions.

Antonia Wierzbicki - Waters
Antonia Wierzbicki is an EMEA marketing manager at Waters. She gained a BSc in Pharmaceutical Science and MSc in Cancer Pharmacology. Following several years working as an analytical chemist in drug development roles within both academic labs and contract research organizations, Antonia has more recently spent time working with analytical chemists to provide solutions using cutting edge technologies to meet their needs and requirements, with a specific interest in ultra-sensitive quantitation of small molecules. Antonia is based in Cambridge UK and keen to connect with like-minded scientists in the field. In partnership with our customers, together, we unlock the potential of science to leave this world better than we found it.

Michael Whaley - MHRA
Michael has been working within the pharmaceutical sector for over 20 years and has experience of the QC and QA of sterile and non-sterile medicinal products at multinational pharmaceutical companies. Michael joined the British Pharmacopoeia 15 years ago as a Senior Scientist and is now Head of BP and Labs Team 2 and has responsibility for co-ordinating the annual BP publication and the in-year updates.

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JPAG future events

Thursday 16th May 2024
Paediatrics Formulation
Royal Society of Chemistry, London

Development of paediatric formulations is linked to many challenges related to safety, efficacy, patient adherence and acceptability. Adherence is a major challenge often dismissed in studies that particularly focus on the safety and efficacy of medicines and can vary depending on the formulation and route of administration e.g. oral, parenteral, inhalation, etc… This symposium focuses on integrated approaches across academia and industry to address challenges in the development, safety and efficacy of paediatric formulations and may include the key themes below:

- Safety of excipients in paediatric formulations
- Age appropriate formulations
- Challenges in paediatric drug delivery and clinical trials
- Advances in oral paediatric medicines (e.g. 3D printed tablets, Alder Hey teddy bear tabs, minitabs)
- Novel drug delivery devices
- Formulation development and characterisation of paediatric formulations
- Analysis of yet smaller levels of analytes and impurities
- Taste assessment of formulation: acceptability versus safety
- Invitro testing using robotic devices
- Inhalation devices for paediatrics

The meeting is open to the submission of abstracts for oral presentations or posters in line with the above proposed key themes.

Register now at www.jpag.org/cp171

Thursday 11th July 2024
Laboratories of the Future
Royal Society of Chemistry, London

The integration of the pharmaceutical industry with Industry 4.0 boosted pharmaceutical development that became digitised and has connected industry in all aspects related to manufacturing, product development and testing. As such automation, robotics, big data and machine learning have become key players in the pharmaceutical product lifecycle. This symposium will highlight the advancement of laboratories in terms of quality and efficiency in Industry 4.0 relating to automation, artificial intelligence, big data, blockchain and robotics. Key themes could include:

- Evolution of pharmaceutical processes from industry 1.0 to 4.0
- Smart manufacturing systems: Pros and Cons
- Enhancing pre-clinical and clinical studies with artificial intelligence
- Fundamentals of in silico testing
- Managing analytical workflow in digital laboratories
- Role of click chemistry in product development
- Robot arms in sample preparation and measurement
- Use of analytical software in Smart Phone Apps
- Machine learning and Artificial Intelligent for analysis of pharmaceutical data
- Development of biomarkers for monitoring human health
- Personalised medicines and dosage forms
- Sustainability – not fully embedded? Driver for change?

The meeting is open to the submission of abstracts for oral presentations or posters in line with the above proposed key themes.

Register now at www.jpag.org/cp172

Thursday 26th September 2024
Continuous Manufacturing and Analytical Strategy
Royal Society of Chemistry, London

Continuous manufacturing offers great promise in improving productivity, efficiency and the intrinsic quality of both active pharmaceutical ingredients and formulated products. This symposium will examine 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.

The meeting is open to the submission of abstracts for oral presentations or posters in line with the above proposed key themes.

Register now at www.jpag.org/cp173

Thursday 5th December 2024
Regulatory Hot Topics IX
Royal Society of Chemistry, London

As per previous years, we'll be highlighting updates to the international regulatory guidance with MHRA and ICH experience. In addition, the topic of mitigating counterfeit and falsified medicines will be discussed. Falsified medicines are fakes that are designed to mimic real medicines whereas Counterfeits are those that do not comply with intellectual-property rights or that infringe trademark law. They impose a serious public health threat globally on consumers and patients. According to the WHO in 2018, counterfeit medicines represented 10% of medicines globally and result in death of around 1 million individuals annually. Until recently, those most frequently found in wealthy countries were expensive 'lifestyle' medicines such as hormones, steroids and antihistamines and in developing countries, medicines used to treat life-threatening conditions such as malaria, tuberculosis and HIV / AIDS. The phenomenon is on the increase with more and more medicines now being falsified including expensive medicines (such as anticancer medicines) and medicines in high demand (such as antivirals). This symposium highlights the problems from industrial and academic perspectives, explores routes into measuring the scale of the problem and proposes solutions for mitigating it. Key themes could include:
- Systematic approaches to measuring the scale of the problem
- Regulatory perspectives for mitigating and fighting the spread of counterfeits
- Illegal online pharmacies and dark web
- Innovation in blockchain and the role it plays in supply chain
- Smart packaging and labelling
- Efficiency of track and trace technology in preventing the spread of counterfeits
- Increasing public awareness towards harm resulting from counterfeit medicines
- Analytical approaches to detecting counterfeit medicines
- Different approach to assessing medicines quality
- Detection of counterfeit medicines outside the lab

The meeting is open to the submission of abstracts for oral presentations or posters in line with the above proposed key themes.

Register now at www.jpag.org/cp175

Interested in any of these meetings?
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- Specialised guidance for pharmaceutical scientists providing answers and guidance for any situation
- Inside advice from trusted experts in every field with our Mentoring and Career support
- Webinars – providing essential advice and guidance from top pharmacists

VENUE:

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

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MEETING FEES:

£195 Members
£295 Non-members
£45 Students and Concessions
See JPAG website for more details

TRAVEL:

The Royal Society of Chemistry is conveniently located in central London with Piccadilly Circus and Green Park Underground stations both just a few minutes walk away.
The nearest train stations are Charing Cross (10 minutes by foot) and Waterloo, Victoria and Kings Cross/St Pancras (10 minutes by taxi).


The RSC at Burlington House, Piccadilly

ACCOMMODATION:

See JPAG website for details

OTHER:

For other information, see our website at www.jpag.org/info

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www.jpag.org/cd170

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