

Formulating the Future: Accelerating Oral Drug Development & Manufacturing

May 31, 2022 | Time: 9:00 am – 5:00 pm

RSC, Burlington House, Piccadilly, London W1J 0BA, UK (United Kingdom)

Oral solid dosage forms remain a preferred option for many pharmaceutical drug developers. However, their successful development and manufacture still presents several unique challenges and opportunities. This event brings together experts in formulation and manufacturing sciences to discuss such challenges and offer solutions related to improving bioavailability, application of different pharmaceutical technologies for dosage form designs, optimizing manufacturing and scaling supply, and accelerating progression to clinic and on to market success.

| | AGENDA | SPEAKERS |
|---------------------|---|---|
| 9:00 am – 9:45 am | Registration and Networking Breakfast | |
| 9:45 am – 9: 50 am | Welcome Note | OneNucleus & Catalent |
| 9:50 am – 10:00 am | Introductions | David Elder, Ph.D. Principal Consultant, David P Elder Consultancy |
| 10:00 am – 10:30 am | Sustaining Accelerated Product Development <ul style="list-style-type: none"> - Ways of accelerating product development and innovative approaches to the development and approval of drug products - The continuum of product development, post pandemic | TBD |
| 10:30 am – 11:00 am | Physiologically based Pharmacokinetic Modelling to Support Drug Development <ul style="list-style-type: none"> - Characterizing drug exposure and predicting how a drug will behave <i>in vivo</i> - Assessing changes in dosage requirements | Jan Neelissen, Ph.D. Associate Director, Science & Technology, Catalent |
| 11:00 am – 11:30 am | Small-Molecule Manufacturing Options for Expedited Programs <ul style="list-style-type: none"> - Optimizing drug performance using conventional and advanced formulation technologies - Flexible drug product manufacturing for adaptive clinical trial – Choosing formulations that are best suited to this approach? | Stephen Tindal Director, Science & Technology, Europe Catalent |
| 11:30 am – 12:00 pm | A Fast-Track Roadmap from Concept to Clinical Batch of HME-Based Drug Products <ul style="list-style-type: none"> - Integrated product development and process screening - Process setup and scale-up via advanced modelling - Transfer of the process to any GMP-certified manufacturing site | Prof. Johannes Khinast, Ph.D. Head, Institute for Process and Particle Engineering at the Graz University of Technology & CEO, Research Center Pharmaceutical Engineering |
| 12:00 pm – 1:30 pm | Networking Lunch | |
| 1:30 pm – 2:00 pm | Transfer and Scale Up Process Steps for Spray Drying <ul style="list-style-type: none"> - Key challenges faced during transfer scale up - Techniques for determining operating conditions at large scale | Nick Hodgson, Ph.D. Head of Development & Spray Drying, EUROAPI |
| 2:00 pm – 2:30 pm | Optimizing Late-Stage Manufacturing Efficiency | Dejan Lamesic, Ph.D. |

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| | <ul style="list-style-type: none">- Key considerations of transitioning an early-stage project to late stage and technology transfer- Understanding the relationship between critical material attributes and critical process parameters | PD Scientific Team Leader, Product Development, Catalent, Schorndorf |
| 2:30 pm – 3:00 pm | Recent Advances in Softgel Dosage Form as a Delivery System <ul style="list-style-type: none">- Advances in softgel capsule shell materials for modified release applications- Lipid-based delivery of peptide therapeutics | Karu Sukuru, Ph.D. Vice President, Rx Product Development, Catalent, Somerset |
| 3:00 pm – 3:30 pm | Improving Clinical & Patient Adherence Outcomes with Orally Disintegrating Tablets (ODTs) <ul style="list-style-type: none">- Opportunities for ODTs as a patient-centric drug delivery tool- Optimizing ODTs for enhanced dissolution and rapid absorption from the oral cavity | Susan Banbury Head of Formulation, Catalent, Swindon |
| 3:30 pm – 3:40 pm | Concluding Remarks | David Elder, Ph.D. Principal Consultant, David P Elder Consultancy |
| 3:40 pm – 5:00 pm | Drink Reception & Meet the Experts | |
