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FOCUSED ON BUILDING AND
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EXTERNAL MANUFACTURERS***

Digital Webinar Draft Agenda

3-4th September 2020

Please Note: All Times Listed are in BST (British Summer Time)

This is a live document that changes daily. For up to date information regarding the forum please contact Emily Shirrefs, Conference Producer, on emily.shirrefs@iqpc.co.uk tel: +44 (0) 207 368 9569

Conference Day 1 – 3 rd September	
11:15	Pharma IQ Welcome
11:20	<p>Case Study: Criteria to Select a CMO</p> <ul style="list-style-type: none"> • Discuss the desired goals and objectives of a new CMO, with an overview of the selection process • Review the acceptance criteria for successful selection and tech transfer • Specifically gain insight on the selection of a CMO for manufacturing HiPo DP, Low Volume Injectables <p>David Caron, VP CMC, Ayala Pharmaceuticals</p>
12:00	<p>MMTS Minitab - From Product Design to Commercial Scale</p> <ul style="list-style-type: none"> • Discuss the significant unmet need to formulate medicines that are easy to administer to children to optimize acceptance, encourage adherence and improve health outcomes • Review how Minitablets can be one of the solutions - also for patients with dysphagia, and when flexible dose adjustments is needed • Identify the growing popularity of Minitablets thanks to recent guidelines and a growing understanding of children swallowing capability, but also because the manufacturing equipment used to produce Minitablet-based dosage forms are the same as those employed in manufacturing of standard tablet • Understand the adjustments and optimization of the manufacturing processes and testing approaches that are required to secure efficiency, robustness, and productivity <p>Giuseppe De Franza, Senior Manager, Technical Services & Operational Excellence, Adare Pharmaceuticals</p>
12:40	Lunch Break
14:20	<p>Going virtual: finding remote solutions for Acino's clients during the pandemic</p> <ul style="list-style-type: none"> • Challenges during the lock-down • Prerequisites for success: proactive communication, openness, flexibility • Case studies on virtual solutions in Business Development and Quality Assurance <p>Yuliyana Manolova, Business Development Manager Contract Manufacturing, ACINO</p>
15:00	<p>Best Practices in Outsourcing CMC Development & Manufacturing for Biologics – A Big Pharma Perspective</p> <ul style="list-style-type: none"> • Review the crucial make-or-buy question – what should you outsource and what should do in-house? • Debate the benefits and risks of outsourcing biologics

	<ul style="list-style-type: none"> • Explore contract making to prevent pitfalls, and learn how to protect your IP <p>Ulrich Rügenapp, Head of Launch Preparation, Bayer AG</p>
15:40	<p>Contract Manufacturing: The Lifeline for a Virtual Company</p> <ul style="list-style-type: none"> • Discover the unique challenges faced by virtual companies at their early stage of growth, whilst they are devoid of any manufacturing capabilities, and identify how CMOs fill this gap to de-risk projects • Discuss guidelines to identify, select, contract and operationally work with CMOs • Illustrate the positive synergies and identify high impact risks that should be avoided by reviewing brief case studies <p>Alain Bernard, Chief Technology Officer, VectivBio</p>
16:20	Close of Webinar Day 1

Conference Day 2 – 4 th September	
14:10	Pharma IQ Welcome and Summary of Day 1
14:15	<p>Operations Digitalisation - Data & System Cross Functional Collaboration and Integration</p> <ul style="list-style-type: none"> • Understand the importance of your data & system constraints in CMOs management • Begin the transformation from a tactical and isolated approach to data & system management, to a cross functional and coherent approach to data management • Identify the realities of a data and system landscape for your company: putting in place a road map to achieving integrated data & system landscape <p>Christopher Pawlak, Global External Manufacturing & Portfolio Strategy and Supply Design Controlling Lead, Bayer AG</p>
14:55	<p>Supplier Risk Management: A Risk Based Oversight over CMO Processes</p> <ul style="list-style-type: none"> • Employ tools to create risk assessment/management action plans • Ensure operational risk management with CGMPs (Current Good Manufacturing Practice) regulations enforced by the FDA • Engage CMOs in risk management activities • Discuss Project Risk Management, Risk Management Planning, Monitoring and Controlling risk and Graphical and Quantitative Methods of Risk Monitoring and Reporting <p>Jayet Moon, Quality Lead, Terumo Medical</p>
15:35	<p>Managing Local Manufacturing Challenges Within Regional Markets</p> <ul style="list-style-type: none"> • Examine a variety of CMO selection processes that can be applied in regional markets such as the LATAM region • Identify the key considerations for a successful alignment of expectations between pharma and external manufacturers • Discuss how to establish a robust development strategy to meet the production timelines on a global scale and avoid critical gaps in production cycles or timing misalignments <p>Luiz Barberini, Head of External Manufacturing - Latin Americas, Bayer AG</p>
16:15	Chairman's Closing Summary And End Of Webinar