

# Association for GXP Excellence

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## Summer Meeting

Date & Time: 22-Jun-2018 9:00am – 3:15pm

Henning's Community Room – Lower Salford, PA

Access AGXPE Website: <http://www.agxpe.wildapricot.org/>

AGXPE SUMMER MEETING, 18 JUN 2018	Presented by:	Time
<b>Coffee and Networking</b>		8:30am – 9:00am
<b>Welcome and Logistics</b>	<b>John Lewis</b> – CEO, AGXPE, Merck	9:00am – 9:15am
<b>Mindful or Mind Full?: Decluttering the Busy Leader's Mind</b> <i>Do you want to be more productive? Less stressed? With increased focus? This presentation will talk about Mindfulness, the practice of bringing your attention to present moment experiences. It is actively paying attention to your thoughts, body sensations and mood in a non-judgmental way. As business leaders we need to take time for ourselves now and again. Mindfulness can help.</i>	<b>Harriet Stein, RN, MS,</b> Founder & Principal of <i>Big Toe in the Water</i>	9:15am – 10:15am
<b>Networking Break</b>		10:15am – 10:45am
<b>Method Development and Qualification with Validation in Mind</b> <i>Inadequate method validation remains an issue during pharmaceutical, biopharmaceutical, and biological product development, approval, and commercial production. It can cause delays in product approval and regulatory problems during commercialization. Avoiding common mistakes ensures the successful validation of analytical methods during Phase III and beyond. This presentation will:</i> <ul style="list-style-type: none"> <li>• Examine how to use the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q2 Guidelines to develop and qualify methods with validation in mind.</li> <li>• Define terminology and describe when method qualification and validation are required.</li> <li>• Provide insight into where method validation fits together with the other considerations to achieve data integrity.</li> </ul>	<b>Judy Carmody, Ph.D.,</b> Founder & Principal Consultant of <i>Carmody Quality Solutions, LLC (CQS)</i>	10:45am – 11:45am
<b>Lunch – Henning's Cafeteria and Buffet</b>		11:45am – 1:15pm
<b>Data Integrity Goes to Court – Are Data Integrity Failures “Material” to a Company's Performance?</b> <i>This session will discuss the very relevant issue of data integrity. We will review current high-profile merger-related litigation occurring between two companies where data integrity issues are the CORE of the dispute. We will also identify what the dispute is; share excerpts of (and assertions within) some of the court documents; review how both companies got there; and discuss lessons to learn from this interesting case. We will also briefly review a comprehensive approach to prevent, fix, and/or remediate data integrity deficiencies within any life sciences organization.</i>	<b>Jack Garvey, Esq,</b> Founder, Principal & CEO of <i>Compliance Architects</i>	1:15pm – 2:15pm
<b>Networking Break</b>		2:15pm – 2:45pm
<b>2018 AGXPE Conference and Expo</b>  <b>Meeting Close</b> <b>AGXPE Organization Update: Financial Update, By-Law update, Future Meetings (1Q2019), Sponsors, Professional Mentoring, other Topics</b>	<b>John Lewis, CEO, AGXPE,</b> <b>AGXPE Board of Directors</b>	2:45pm – 3:15pm