Wednesday, 18 June

EDT Daylight Time (UTC -4:00)

<table>
<tr><td>17:30 – 18:45</td><td colspan="2">Sponsors/Networking</td></tr>
<tr><td>18:45 – 19:15</td><td colspan="2">Dinner Served</td></tr>
<tr><td>19:15 – 19:45</td><td colspan="2">Opening Remarks</td></tr>
<tr><td rowspan="4">19:45 – 20:50</td><td colspan="2">Speaker Presentation and Q&A</td></tr>
<tr><td>19:45 – 20:15</td><td>Multiproduct ATMP GMP Manufacturing Facility Design Impacts on Contamination Control Strategy

The 2023 update to EU GMP Annex 1 has intensified the emphasis on a comprehensive Contamination Control Strategy (CCS) for GMP facilities manufacturing sterile drugs. This is especially relevant for multi-product facilities producing Advanced Therapeutic Medicinal Products (ATMPs) within shared GMP infrastructure. Heightened regulatory attention on CCS has raised the standards for GMP facility design, prioritizing product segregation and cross-contamination prevention. This affects the design of new multi-product facilities and can also significantly impact existing Clinical facilities seeking Commercial regulatory approval that were designed before the Annex 1 revision.

• Jeff Gilmore , CEO, cGMPnow</td></tr>
<tr><td>20:15 – 20:45</td><td>Good Design and Operational Principles for Multi-Product Facilities

Multiproduct facilities require robust design and qualification in order to meet regulatory requirements and customer expectations. Facility planning starts at the design phase, with many aspects to consider when deciding on HVAC and cleanroom design and qualification. Considerations include what might be the best design to meet both US and ex-US requirements in the same plant, whether a dedicated HVAC system is required, and what are best practices for cleanroom and environmental commissioning and qualification. Concurrently, firms should be developing processes for good controlled operation and facility monitoring, to ensure the multi-product facility remains within the validated state.

• Scott Corbin , President, Partner, Gray Matter Partners</td></tr>
<tr><td>20:45 – 20:50</td><td>Q&A</td></tr>
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