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## Dynamic Challenge of Sealing Performance of Container System for Biologic and Cell & Gene Therapy at Low Temperature

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For biologic and cell & gene therapy, there has been a challenge in the container sealing performance for cold storage and shipment. Container closure integrity is essential for biologic and cell & gene therapy packaging. The integrity performance must be maintained in real time and over time throughout the entire drug product lifespan. This presentation demonstrates that container sealing performance will dynamically change inherently by itself. Our modeling evaluation and experimental data determined that the time temperature transition critically impacts container sealing performance. The experimental results agree very well with time temperature superposition modeling results, demonstrating that the sealing performance inevitably changes over time together with dynamic temperature transition. The significant loss of sealing performance at lower temperature transitions could potentially contribute significant risk to drug product integrity at low storage and transport temperatures. The present work provides a new, integrated methodology framework and some fresh acumens to the biologic and cell & gene therapy industry for practically and proactively considering, designing, setting up, controlling, and managing container stopper sealing performance throughout the entire sealed drug product lifespan. Particularly, container sealing performance at lower temperature needs to be properly addressed, evaluated, calculated, simulated, predicted, tested, and assessed through an integrated system approach for critical data-driven risk management.

### RECENT PUBLICATIONS:

1. Qingyu Zeng, Anthony Bucci, and Le Ho, Time Temperature Superposition Evaluation and Modeling for Container Closure System's Seal Performance at Low Temperatures, PDA Journal of Pharmaceutical Science and Technology, July 2019.
2. Qingyu Zeng and Xia Zhao, Time-Dependent Testing Evaluation and Modeling for Rubber Stopper Seal Performance, PDA Journal of Pharmaceutical Science and Technology, 2018, 72 134-148.
3. Qingyu Zeng, Considerations for Achieving an Optimal Performance Window for Container Closure Systems, PDA Letter, PDA Letter, January, 2019.
4. Qingyu Zeng, Critical Time- & Temperature- Dependent Container Closure Integrity Through the Sealed Drug Product Life Cycle, invited presentation to PDA Parenteral Packaging, Rome, Italy, 27 – 28 February, 2018.
5. Qingyu Zeng, Le Ho, Lauren Orme, & Arjun Sachdeva, Data-driven Control Strategy for Critical Drug Container Closure System Performance at Digital Age, podium presentation to INTERPHEX Technical Conference, New York City, April 17 – 19, 2018

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## Biography

Dr. Qingyu Zeng has 20+ years of working experience. Throughout his career, Qingyu has served in various roles such as fellow, technical director, and advanced technology platform leader with various responsibilities to strategically lead multi discipline team efforts to identify, evaluate, and develop cutting-edge products and core technologies for successful commercial platform deployment. He holds more than 10 granted patents. Qingyu graduated with BS and MS from Donghua University in China and received his Ph.D. in Polymer Science from North Carolina State University with ΦΚΦ honor, and completed his EMBA from Ohio State University.

## Notes: