

# PDA Letter

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## Tackling Sterility Concerns of Compounding

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Prior to 2012, most Americans had never heard of compounding pharmacies, however, in the wake of the New England Compounding Center (NECC) tragedy, this changed overnight. Following this event, calls for greater control over compounding pharmacies spurred legislative activity in the U.S. Congress. State boards of pharmacy and the U.S. FDA increased regulatory scrutiny of these operations, resulting in closures of additional compounding pharmacies in multiple states. In addition, PDA has also been involved with compounding pharmacy regulation, notably with its review of the FDA draft guidance, *Current Good Manufacturing Practice – Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act*.

Historically, the role of compounding pharmacies has been to make drugs prescribed by doctors for specific patients with needs that cannot be met by commercially available drugs. But in the last several years, compounding pharmacies have stepped up their production in an effort to ease drug shortages and are now being utilized on a larger scale as drug manufacturing problems result in shortages of critical drugs. Given the sterility concerns at some compounding pharmacies, increased attention has been given to sterile manufacturing as it places extreme emphasis on equipment, personnel, quality systems, procedures and practices to obtain the largest sterility assurance possible, meaning compliance with USP <797> Pharmaceutical Compounding Sterile Preparations.

This year's *PDA Aseptic Processing – Sterilization Conference* will again look at recent updates and insight on compounding regulations. Given the high risk to patients and increased awareness by the public this topic continues to be an important part of the this conference. This time, two of the leading experts in the field, **Rich Kruzynski** President, Pharmedium Services, and **Ken Latta**, President, Health System Consulting Group and Gates Healthcare, will delve further into this important topic.

For more information about this conference, please visit [www.pda.org/aseptic2015](http://www.pda.org/aseptic2015). For information about PDA Education courses following the conference, go to [www.pda.org/sterilizationcourses](http://www.pda.org/sterilizationcourses). 🍷

For more information, contact [USpharma@nsf.org](mailto:USpharma@nsf.org) or visit [www.nsfhealthsciences.org](http://www.nsfhealthsciences.org)

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