



# **Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products**

*Dennis Jenke*

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Compatibility of Pharmaceutical Products and Contact Materials

Dennis Jenke

Important safety aspects of compatibility for therapeutic products and their manufacturing systems, delivery devices, and containers

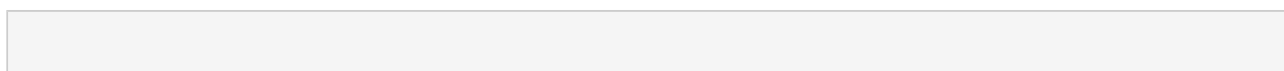
*Compatibility of Pharmaceutical Products and Contact Materials* helps pharmaceutical, toxicology, analytical, and regulatory affairs professionals assess the safety of leachable and extractable chemicals associated with drug product packaging, manufacturing systems, and devices. The most comprehensive resource available, its coverage includes the strategies, tactics, and regulatory requirements for performing safety assessments, along with the means for interpreting results.

Structured around a logical framework for an extractables and leachables safety assessment and closely linked to the pharmaceutical product development process, *Compatibility of Pharmaceutical Products and Contact Materials* directly addresses the fundamental questions of "what activities need to be performed to completely, efficiently, and effectively address the issue of product safety from an extractables and leachables perspective?" and "when do the various required activities need to be performed?" Specifically, the chapters describe:

- Pertinent regulations and practical ways to meet guidelines
- Coordinating manufacturing, storage, and delivery systems development and qualification with therapeutic product development
- Materials characterization and the materials screening process
- Component and/or system qualification (illustrated by several case studies)
- Performing validation/migration studies and interpreting and reporting the results
- Creating a product registration dossier and putting it through regulatory review
- Product maintenance (Change Control) from an extractables and leachables perspective
- Likely future developments in extractables and leachables assessment

Additionally, the book's appendix provides a database, including CAS registry numbers, chemical formulas and molecular weights of extractable/leachable substances that have been reported in the chemical literature.

Detailing the interconnected roles played by analytical chemistry, biological science, toxicology, and regulatory science, *Compatibility of Pharmaceutical Products and Contact Materials* supplies a much-needed, comprehensive resource to all those in pharmaceutical product or medical device development.



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#### **Ernestine Worrell:**

Playing with family within a park, coming to see the marine world or hanging out with good friends is thing that usually you may have done when you have spare time, then why you don't try thing that really opposite from that. One activity that make you not feeling tired but still relaxing, trilling like on roller coaster you are ride on and with addition details. Even you love Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products, it is possible to enjoy both. It is very good combination right, you still wish to miss it? What kind of hangout type is it? Oh seriously its mind hangout folks. What? Still don't get it, oh come on its named reading friends.

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