Validating Medical Packaging

Ronald Pilchik
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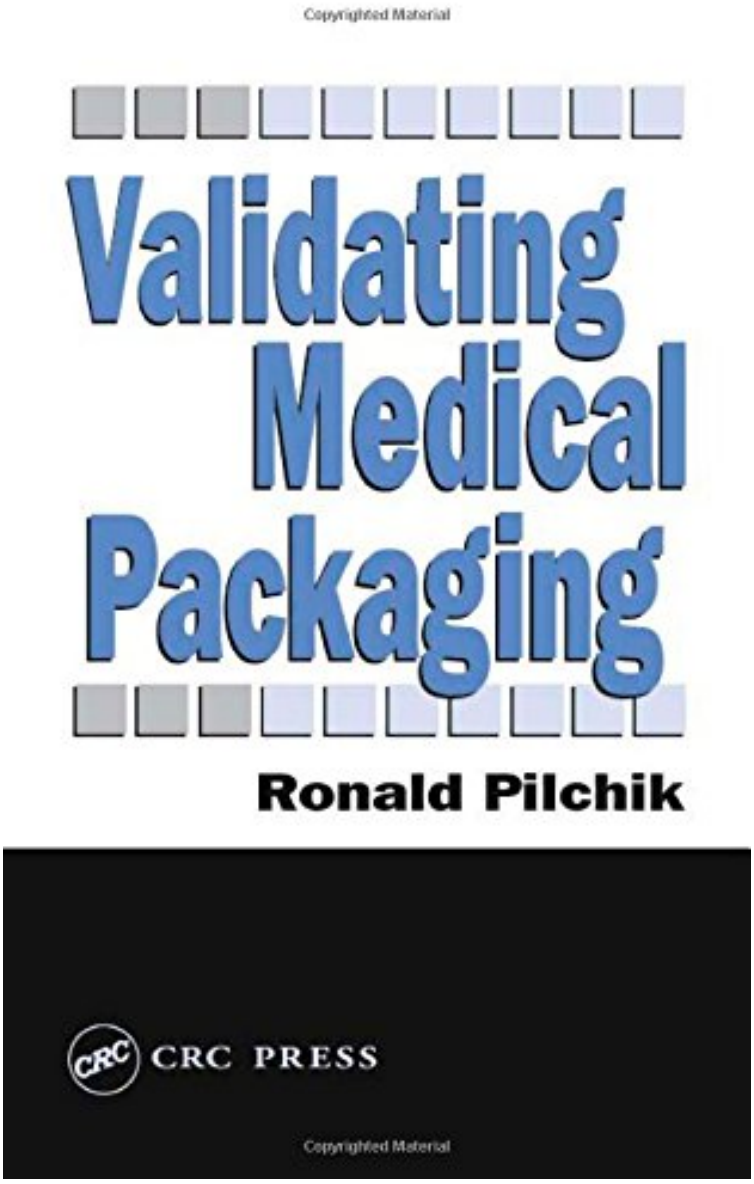

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Ronald Pilchik : Validating Medical Packaging before purchasing it in order to gage whether or not it would be worth my time, and all praised Validating Medical Packaging:

0 of 0 people found the following review helpful. Great book!By JimGreat walk-thru of all the basics. It offers the kind of guidance that is so valuable for the recent practitioner or infrequent user of these techniques and procedures.0

of 0 people found the following review helpful. Five StarsBy stevemwGreat, concise book but I still think the subtitle should have been, "Hey, Check Out My Package".

According to the FDA Quality System Regulations, manufacturers must ensure that "device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution." As specific as this statement is, the FDA does not provide instructions on how to achieve their standards. Validating Medical Packaging demystifies the validation procedure for medical device packaging by providing specific examples and templates for creating and maintaining a validation file.About the author: Ronald Pilchik has over 30 years of experience in the healthcare manufacturing industry. As principal of the Techmark Group, he provided consulting services to diverse multinational manufacturers on selecting, developing, and validating medical packaging compatible with their sterilization requirements. He has been chairman of the healthcare packaging section of TAPPI, the packaging committee of HIMA, and a member of AAMI's ISO198 working group on packaging. Mr. Pilchik is program chairman of the HealthPack Conference Series on medical device packaging.