Columbia Basin Section
ASQ Excellence Through Quality™

Invitation from
ASQ Palomar Section
November 9, 2022 Virtual Meeting

WE ACHIEVED HONORABLE MENTION IN 2020!
PERFORMANCE EXCELLENCE PROGRAM

DATE:

Wednesday,
November 9, 2022

This is a virtual/Zoom meeting. Log-in information will be provided on the registration confirmation email.

Time:

6:30 pm – 8:00 PST
(opens for networking at 6:00 pm)'

(check website to confirm times)

Cost: Free for ASQ members and non-members

To register for this meeting and obtain the Zoom link and sign-in information, send an email.

Attendance at this meeting earns 0.5 RUs toward ASQ recertification.

NOTE: Be sure to use the same email address to join the virtual meeting as you use when registering to receive the RUs. You must register for the event and join virtually to receive RUs.

For more information about Palomar ASQ Section 708, click here.

For more information about our local Columbia Basin ASQ section and future upcoming events: www.asq614.org/

What does Packaging Sterile Medical Devices with IS0 11607 Truly Mean?

Jan Gates
Owner and Consultant, PackWise Consulting

ISO 11607 is the principal guidance document for validating terminally sterilized medical device packaging systems. Packaging must comply with ISO 11607 to satisfy European regulations and obtain a CE Mark. ISO 11607 is also an FDA Recognized Consensus Standard.

The ISO 11607 standards were the first to place packaging on the same level (importance) as a product.

Packaging for medical devices is not intuitive and can cause a lot of headaches for a company, especially with a regulated and terminally sterilized product.

Delivering a safe, functional, easy-to-use product to customers is impossible without good packaging planning (though many companies try without experienced packaging engineers to assist).

This talk provides an overview of the ISO 11607 standards and the methods developed for good packaging.

About the speaker: Jan Gates is the owner and principal packaging engineer of PackWise Consulting in southern California. She has 35+ years of experience in package engineering for foods, pharmaceuticals, detergents, and medical devices. She has worked as an individual contributor and has also led teams for packaging material and systems design and development, ensuring regulatory, product protection, and customer use requirements are met. Jan's work includes production optimization, validation, and minimal packaging for sustainability with cost reductions always in mind. She previously worked for Bristol Myers Squib, Conagra, Lever Brothers, Dade Behring, and Abbott Vascular.

Jan works with ASTM D10 and F02 committees for rigid/flexible packaging and environmental package testing. She serves as a US representative on various ISO TC 122 committees for packaging testing, labeling, and product shipment, and was a task group lead with AMMI on a US guidance document for compliance with ISO 11607-1/-2 (packaging for terminally sterilized medical devices); the guidance document was converted to ISO/TS 16775. Jan has been a member of IoPP (Institute of Packaging Professionals) for many years and an IoPP Medical Device Packaging Technical Committee member. She holds a BS in Food Science and MS in Packaging from Michigan State University.