

Webinar on

Qualification and Control of Contract Manufacturers (CMO) Based on Practical Experience

Learning Objectives

- CMO management principles*
- Supplier quality categories*
- Approved Vendor List (AVL)*
- Phases of CMO selection from initial telephone inquiry to a quality survey to qualification audit*
- Planning a qualification audit-establishing evaluation team*
- Conducting a qualification audit-key points to evaluate*



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- Decision factors for selecting CMO-key practical points*
- Distinctive technical competence*
- Optimum CMO size*
- Risk of educating future competitor*
- Key points for the contract*
- Change approval by both CMO and company*
- Quality Agreement*
- Dealing with uncooperative suppliers.*
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This webinar will describe a compliant program based on regulatory requirements and the author's personal experience in qualifying over 40 CMO's in the medical device industry.

PRESENTED BY:

Edwin retired from the industry after 30 years in management of the development of medical device products and development of company Quality Systems. He was involved in the development of products such as IVD devices, kidney dialysis systems, and inhalation devices.

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

CMO's must be selected following a rigorous formalized procedure.

This webinar will describe a compliant program based on regulatory requirements and the author's personal experience in qualifying over 40 CMO's in the medical device industry. The control of changes is one such topic that is complex. Lessons from practical experience show methods that will prevent a development program from becoming uncompliant.



Who Should Attend ?

Engineers

Engineering management

Purchasing

Quality Assurance

Manufacturing



Why Should You Attend ?

Regulatory agencies require that companies carefully select and manage suppliers and contract manufacturers. The responsibility for product quality and safety remains with the company. It cannot be delegated to the CMO.

There are many practical concepts for selecting and managing CMO's that are not found in the regulations that will be explained such as procedures for change control and criteria for selecting a CMO.



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