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Good Practice Guide: Technology Transfer 3rd Edition - ISPE

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Good Practice Guide: Technology Transfer (Third Edition)

ISPE Good Practice Guide: Technology Transfer 3rd Edition. 10 February 2020. Transfer of manufacturing processes and analytical procedures between facilities or laboratories is a necessary part of pharmaceutical development and commercialization. Technology transfers take the outputs of process...

Technology Transfer | ISPE | International Society for ...

ISPE announced the release of their latest Guide, ISPE Good Practice Guide: Technology Transfer 3rd Edition. This Guide provides industry good practices for successful and efficient execution of technology transfer projects. "Transfer of manufacturing processes and analytical procedures between facilities or laboratories is an essential part of pharmaceutical development and commercialization," said John Bournas, ISPE CEO and President.

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Critical activities and success factors required for an effective and efficient technology transfer. Requirements for planning, execution, and assimilation of technology and knowledge transfer. Attendance suggested for: Years in industry: 0-4 to 5-14. Ideal audiences are those with 2+ years of industry experience that want to supplement their industry knowledge about a specific topic (s)

Pharmaceutical Technology Transfer - ISPE

Overview. Developing effective protocols for technology transfer is essential for addressing current industry challenges and evolving business needs. As the industry continues to experience changes, technology transfer for active pharmaceutical ingredients (APIs), finished dosage forms and analytical methods between development and manufacturing sites and contract manufacturing organizations (CMOs) has become increasingly important. This training course on Pharmaceutical Technology Transfer ...

Pharmaceutical Technology Transfer Training Course - ISPE

Where To Download Ispe Guidelines Technology Transfer Good Practice Guide: Technology Transfer 3rd Edition - ISPE Technology transfers take the outputs of process or method development activities and transfer the knowledge to a different location where a process or analytical procedure will be operated. This Guide presents industry good Page 6/30

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The ISPE Good Practice Guide: Technology Transfer 3rd Edition presents industry good practices for successful and efficient execution of technology transfer projects. It intends to achieve a balance between risk management and cost effectiveness while aligning with applicable regulatory expectations.

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These guiding principles on transfer of technology are intended to serve as a framework which can be applied in a flexible manner rather than as strict rigid guidance. Focus has been placed on the quality aspects, in line with WHO's mandate. 1.1 Transfer of processes to an alternative site occurs at some stage in the life-cycle of most products, from development, scale-up, manufacturing, production and launch, to the post-approval phase. 1.2 Transfer of technology is defined as "a ...

Annex 7 WHO guidelines on transfer of technology in ...

The ISPE Good Practice Guide: Technology Transfer 3rd Edition presents industry good practices for successful and efficient execution of technology transfer projects. It intends to achieve a balance between risk management and cost effectiveness while aligning with applicable regulatory

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Scale-up & Technology Transfer as a Part of Pharmaceutical Quality Systems George P. Millili, Ph.D.
Senior Director Pharmaceutical Commercialization

Technology Transfer and Pharmaceutical Quality Systems

transfer of technology as described in the Introduction to this guideline. The intention is to address the basic considerations needed for a successful transfer in order to satisfy the regulatory authority defined for the transfer process. 2.2 The recommendations provided in this guideline apply to all dosage forms.

WHO GUIDELINE ON TRANSFER OF TECHNOLOGY

Technology transfers take the outputs of process or method development activities and transfer the knowledge to a different location where a process or analytical procedure will be operated. This Guide presents industry good practices for successful and efficient execution of technology transfer projects.

ISPE Good Practice Guide: Technology Transfer

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