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

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forms.

Streamlining Technology Transfer

One of the co-authors of the ISPE PQLI good practice guide (2011), a well respected speaker & trainer at different conferences, seminar & workshop. Key Takeaways. Learn and explore the technology transfer scope, team & charter (introduction & explanation of tools), technology transfer process & standard operating procedures

AN INTERNATIONAL GOOD PRACTICE GUIDE FOR PHARMACEUTICALS ...

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transfer is the process by which the manufacturing process and analytical method are transferred from one manufacturing unit to another unit or from R&D to manufacturing unit.

Technology Transfer | ISPE | International Society for ...
Technology transfer of drug product (dosage forms manufacturing processes) This third edition of the ISPE Good Practice Guide: Technology Transfer, highlights the following: Alignment with science and risk-based (Quality by Design (QbD)) principles described in ICH Q8 Pharmaceutical Development, ...

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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 or method development activities and transfer the knowledge to a different location where a process or analytical procedure will be operated.

WHO GUIDELINE ON TRANSFER OF TECHNOLOGY

As each transfer project is unique these guidelines can not cover all possible situations. These guidelines do not provide guidance on any legal, financial or commercial considerations associated with technology transfer projects. 22 Prepared by Drug Regulations a Not for Profit Organization 23.

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Good Practice Guide: Technology Transfer (Third Edition)

This third edition of the ISPE Good Practice Guide: Technology Transfer, highlights the following: Alignment with science and risk-based (Quality by Design (QbD)) principles described in ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management, ...

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2.5 Because each transfer project is unique, the provision of comprehensive set of guidelines is beyond the scope of this document. 2.6 These guidelines do not provide guidance on any legal, financial or commercial considerations associated with technology transfer projects. 3. Glossary

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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

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execution of technology transfer projects.

Technology Transfer Guidelines for Pharmaceuticals ...
Welcome to the ISPE Guidance Document Portal. Produced by pharmaceutical manufacturing industry professionals, ISPE Guidance Documents provide the practical, "real-world" information you need to help your company build on current best practices to meet and exceed regulatory standards.

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3. Technology Transfer: Organisation Strategy and Planning 25

Steve Burns and Mark Gibson Introduction 25 Stages of the

Technology Transfer Process 26 Stage 1: Pre-technology

Transfer Preparation 26 Technology Transfer Strategies 29

Stage 2: Scale-up and Establish Process at Commercial Scale 32

Stage 3: Plan and Perform Process Validation 33 Management

of Change 34

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Biopharmaceutical Technology Transfer ICH Q10 paragraph
3.1.2 ISPE GOOD PRACTICE GUIDE TECHNOLOGY
TRANSFER 3rd EDITION Technology transfer is the
execution (technical and process knowledge) and management
of all activities required to successfully reproduce the
manufacture of a

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