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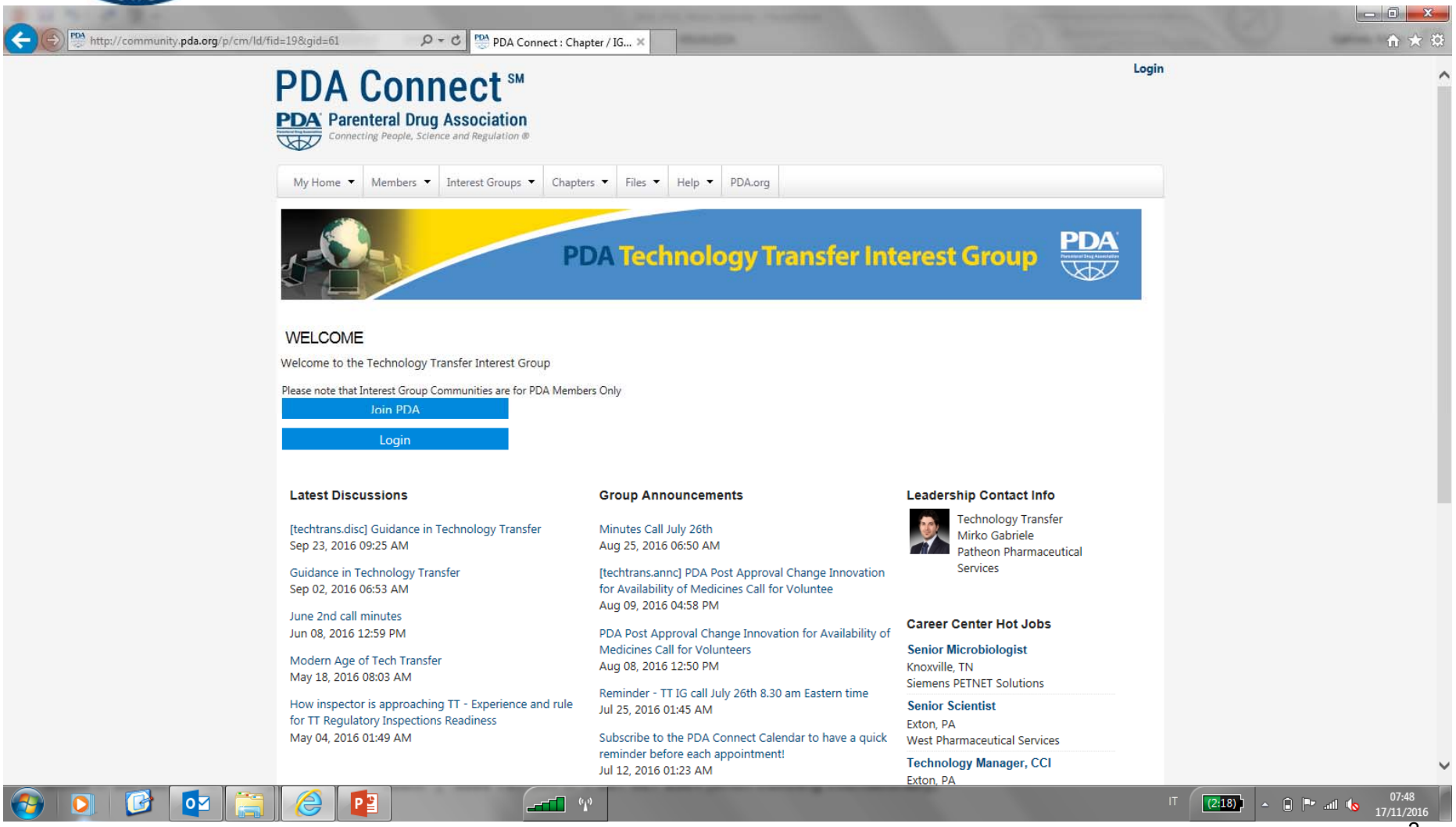
# Technology Transfer IG

January 2018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17/11/2016

# TT IG – *WHY* an IG on TT

The processes of Technology Transfer in pharma are becoming more and more important with a strong link to Company wellness and performance to *ensure the robust distribution of medicines to the patients.*

As a consequence the Technology Transfer IG was ***launched in 2016***. It's main objective is to capture the opportunity given by benchmarking industry experience in Technology Transfer in order to provide useful information through Technical Reports, articles, position papers, training sections, and lectures.

- Complexity from virtual operations
- Emerging Technologies
- Integration of Risk Managment

# TT IG – Our Vision and Goals

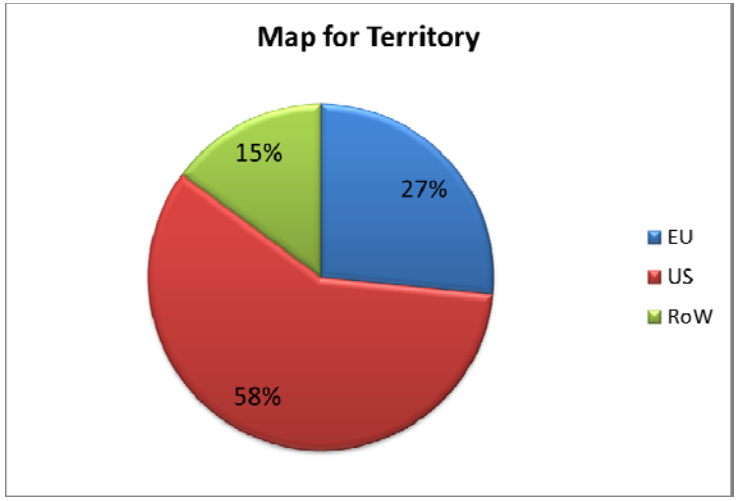
- ***Our Vision*** as a Team is to have all the TT Experts connected in an open system to focus on best practices and innovation.

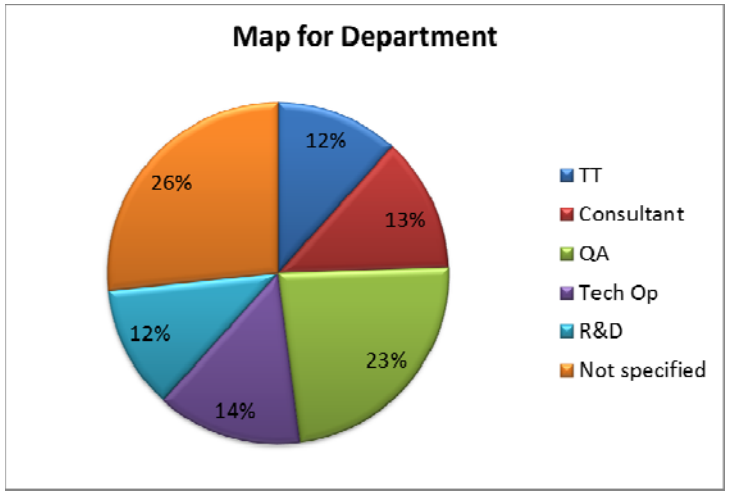
- Technology Transfer is a multidisciplinary subject, therefore the TT IG will set as an objective for the future to be more and more ***connected with the other IGs*** with the main purpose to leverage their experience and identify new ideas, needs and opportunities through networking.

- ***Quality Framework*** and Quality Compliance is a must in Technology Transfer, therefore we will proceed in our mission to analyze and absorb Quality musts and nice to haves.

# TT IG – mapping

- 199 members registered till today
- 50% increase in the last 6 months
- Big community with well territorial and expertise distribution
- *Main opportunity…Active partecipation to be incereased*!



# TT IG Group EU Leader

## Production Director – Patheon Ferentino Site

– Based in Ferentino Site (close to Rome)

- Pharmaceutical Chemist by training, got my degree in Rome
- Executive MBA in Pharma Business Administration
- +12 years of experience in Pharma
- Main areas R&D, QC, TT and Business Management
- Global (EU & US) Technology Transfer Responsible in Patheon , as last exp.

The part that I like more about my job is that "*We can always make the difference for our stakeholders*"

Joining the PDA TT Interest Group and benchmarking different experiences is key for improve and succeed!

I love scuba-diving, playing guitar, reading fantasy books and business/financial newspaper.

Two sentences summarize my professional approach:

- *"Fabrum esse suae quemque fortunae"* adding to the original quote *"good teamwork helps a lot*!"
- *"Ad maiora semper"*

# TT IG Group US Leader

VP, QC Operations
– Biogen, Inc., *Responsible for Global QC Operations*

- B.S. Degrees in Biochemistry and Biology
- Global Executive MBA – Fuqua Business School, Duke University
- 25+ years pharma experience
- Prior experience includes Glaxo and Novo Nordisk

Positions in Biogen include site Quality Director, Corporate Quality responsible for audits and QMS and QC management.

PDA Interest Groups are critical for sharing and benchmarking within industry – I have always found my participation greatly rewarding and informational.

Couple of thoughts around Tech Transfer:

- *It is industry's time to leverage technology to improve TT processes*
- *A focus on scientific risk based paradigms will be critical to success*

# Why Discuss about TT

- Incredible **increase** of number of **Technology Transfer projects** (TTP) in the pharmaceutical environment, both internal & external and consequent increase of attention on Technology Transfer (TT) handling by Authorities;
- Project **complexity** is growing day by day;
- **Risks of failure** is always high;
- **Quality Risk Management (QRM) & Project Management (PM)** skills and knowledge are fundamental for success!

# Why Discuss about TT

**$1T**

Global Rx sales by 2020

**$160B**

Global pharma and biotech R&D spend by 2020

**60 to 10**

Shrink in number of Pharma players due to M&A in the last 20 years

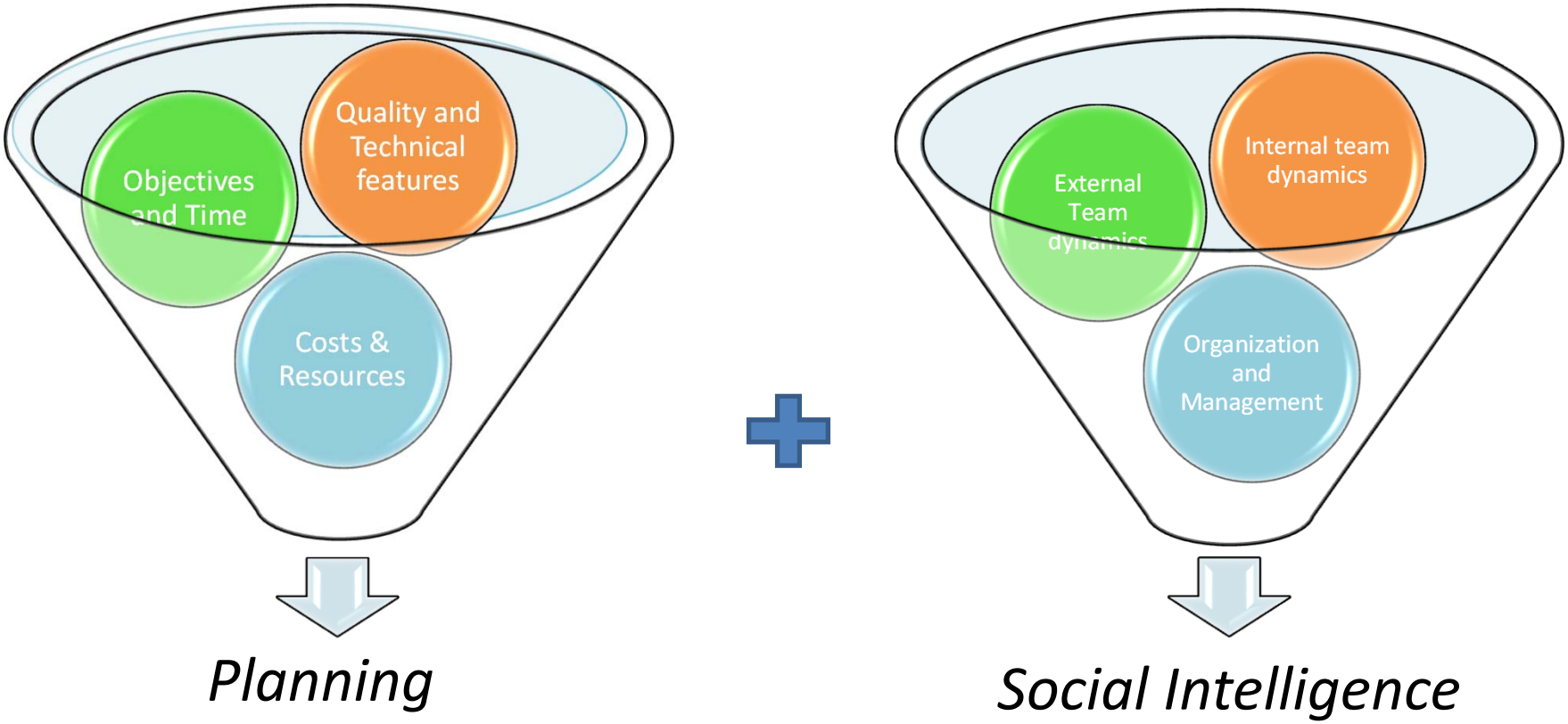
***TT IS AND WILL BECOME A MORE CRITICAL BUSINESS NEED, A "BEST TO BEST DEAL" WITH CUSTOMERS, TOP PLAYERS LOOKING FOR CDMO TOP PLAYERS***

# Technology Transfer main concepts

*Which are the main Project risks?*

1. *Project Scope missed or misunderstood*
2. *Underestimating of new site/process impact on product attribute*
3. *Lack of product/ process understanding*
4. *Lack of communication*
5. *Lack of escalation process*
6. *Wrong extimation of time/resources/costs*
7. *Lack of engagement of Team members*
8. *Lack of performance monitoring during execution*

# Technology Transfer – Focus Area




*Planning*

*Social Intelligence*

# Technology Transfer main concepts

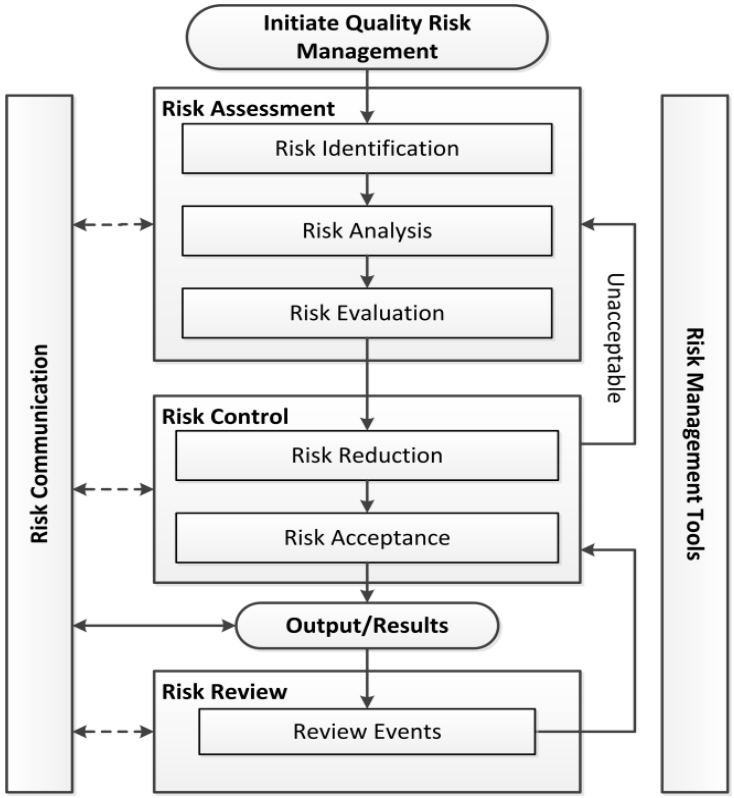
***How to reduce Project Risk…***

# Technology Transfer – Social Intelligence

- Technical Skills
- Planning
- Multitasking and Organization
- Flexibility
- Troubleshooting
- Negotiation
- Goal oriented

# Technology Transfer – Process/Product Risks

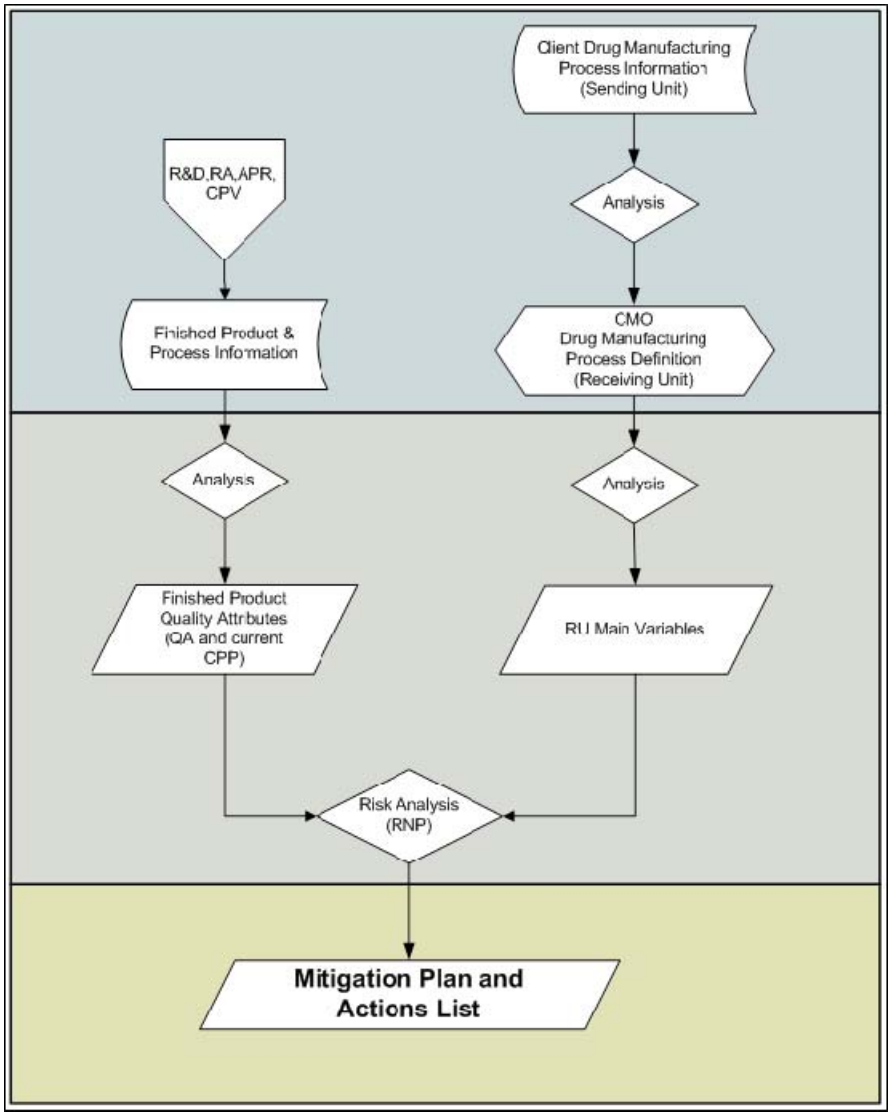
The quality risk management (QRM) is “a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle.”



# Technology Transfer – Risk Management

| Stage Gate | Strategy | Analytical and Quality Control Testing | Regulatory | Process | Facilities/ Engineering | Risk Management and Components |
|---|---|---|---|---|---|---|
| 1 Planning | Perform preliminary risk assessment prior to beginning late-phase development using risk ranking and/or preliminary hazards analysis approach. | | | | | |
| 2 Process Readiness | Update preliminary risk assessment (transition to PHA) | Update risk assessment (transition to PHA) for SU and RU readiness for AMT | Risk mitigation through SLA and quality agreement between SU and RU | Update risk assessment (transition to PHA) for manufacturability of late-phase development process | Update risk assessment (transition to HAZOP) for operating process at manufacturing site | Update risk assessment (transition to PHA) for RMs/ components, including assessment of the impact of any changes in the suppliers or manufacturing sites of the RMs |
| 3 TTP implementation and Qualification | Review and update risk assessment/PHA from stage gate 2 if necessary. Mitigate identified high risks. | | | | | |
| 4 Licensure & Manufacturing | Convert PHA risk assessment from stage gate 3 to FMEA/FMECA risk assessment, including re-evaluation of risk ranking after risk mitigation plan implementation | | | | | |
| | Update risk assessment from stage gate 4 for commercial process | Complete risk assessment for SU and RU readiness for AMT | Risk mitigation through SLA and quality agreement between SU and RU | Update risk assessment for manufacturability of commercial process | Update risk assessment (HAZOP) for operating process at commercial site | Update risk assessment for RMs/components, including assessment of the impact of any changes in the suppliers or manufacturing sites of the RMs |

# Technology Transfer - Risk Management



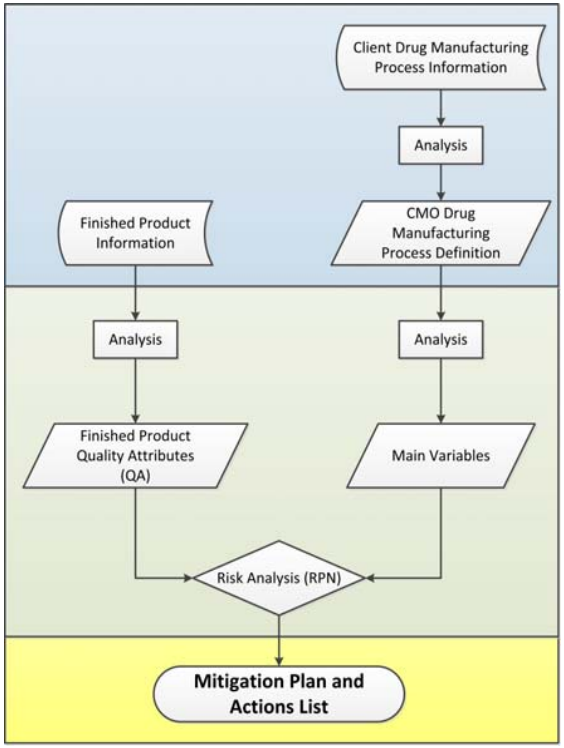

***Data collection***

***Data evaluation***

***Data use***

# Technology Transfer - Risk Management

Our Risk Assessment and Mitigation approach is based on several Source of information, linked to create a TT Starting Story




**Source 1** – Definition of the Main Process Variables of the product (SU -> RU) *(examples below)*

| List of main items considered for the evaluation | Relative Variables | | |
|---|---|---|---|
| Process | Mixing<br>Holding<br>Compounding<br>Grade C filtration<br>Grade A filtration | Filling<br>Stoppering<br>Crimping<br>Solution transfer<br>Steam terminal sterilization | Identification<br>Wrapping<br>Visual inspection<br>Secondary packaging<br>Line cleaning |
| Primary packaging and GMP materials | Stoppers<br>Vials<br>Seals | Filters<br>Disposable tubes<br>Disposable bag | Fixed tube<br>Gasket |
| API and excipient attributes | API pH<br>API appearance | API density<br>API osmolality | Excipient attributes |

**Source 2** – Definition of the Quality Attributes (RU) *(examples below)*

| Quality Attribute | | |
|---|---|---|
| Appearance | pH | Volume in container |
| Identity | Density 20°C | Cosmetic appearance |
| Assay | Osmolality | Sterility |
| Impurity | Particle matter | Endotoxins |

# Technology Transfer - Risk Management

Risk Assessment and Mitigation Approach:

- is part of part of Company DNA, therefore application is a must for all our TTs and during the whole project lifecycle;
- Has to be in line with the current regulatory guidance, GMP and based on scientific sound
- Has to be managed by appropriate flexible, robust and efficient tools
- Is a multifactorial exercise that takes in considerations internal and external variables of the project/process/product/lines
- Provides a clear path forward starting with QbD and development (where necessary) and ending with a reproducible, efficient and in quality market supply

| Analysis | | | | Risk Priority Number Evaluation | | | | Mitigation Plan |
|---|---|---|---|---|---|---|---|---|
| Item | Variable | QA Impacted | Potential criticality/cause of lack of quality attribute description | Severity | Occurrence | Detection | RPN | Consideration/Action |
| Primary Packaging & GMP materials | Stoppers | Impurity | An impurity from the stopper can modify the solution chemical profile | 3 | 2 | 3 | 18 | The stopper components have been chosen by the SU during the development studies. |
| | | | The coating material can modify the chemical solution profile | 3 | 2 | 3 | 18 | The same stoppers will be used to guarantee no anomalous interaction with stopper coating and rubber. |
| | | Appearance | Substances released from the stopper or from the coating can induce flocculation or coagulation events in the solution | 3 | 2 | 1 | 6 | Stability data were collected by the SU; no interaction issues were reported to RU. |
| | | | Substances released from the stopper or from the coating can modify the appearance of the solution | 3 | 2 | 1 | 6 | |
| | | Sterility | The bioburden of the stopper can impact the effectiveness of currently used and validated sterility cycles | 3 | 1 | 3 | 9 | A risk assessment will be done to compare the several stoppers currently used in RU with the SU stoppers, to evaluate the possibility to use a sterilization cycle already validated. In the case in which no comparable stoppers are found, a new stopper sterilization cycle will be validated. |
| | | Particle Matter | Release from the stopper may impact the particle matter profile of the solution | 3 | 2 | 3 | 18 | A final 100% visual inspection will be done. Vials with a particle matter defect will be rejected. |
| | Vials | Impurity | Impurities released from the glass can impact the solution profile | 3 | 2 | 3 | 18 | Type I glass, USP/EP grade will be used. The validation batches produced will be analyzed via stability study. All release tests will be repeated regularly during the stability program to confirm no anomalous changes to the system profile. |
| | | | Leachables and extractables from the glass can modify the chemical profile of the solution | 3 | 2 | 3 | 18 | |
| | | Appearance | Leachables, extractables, and ions can induce flocculation or coagulation of the system | 3 | 2 | 1 | 6 | |
| | | Cosmetic Appearance | Vials of finished product can be rejected for cosmetic defects | 2 | 2 | 1 | 4 | *No further actions are needed.* Incoming statistical checks will be done on each lot of vials prior to use. An agreement with the supplier is in place that defines appropriate AQLs for each defect. These AQLs are in line with the cosmetic requirements received by the SU. |

| Analysis | | | | Risk Priority Number Evaluation | | | | Mitigation Plan |
|---|---|---|---|---|---|---|---|---|
| Item | Variable | QA Impacted | Potential criticality/cause of lack of quality attribute description | Severity | Occurrence | Detection | RPN | Consideration/Action |
| Process | Mixing, Compounding | pH | Dissolution time insufficient for complete dissolution and an homogenous system | 3 | 3 | 1 | 9 | During the Performance Qualification, the mixing device of the tank used in the RU will be challenged. |
| | | Osmolality | Dissolution speed insufficient for complete dissolution and an homogenous system | 3 | 3 | 1 | 9 | Mixing studies will be agreed with the SU and performed during the engineering batch. |
| | | Appearance | Mixing system not appropriate to guarantee uniform batch mixing | 3 | 3 | 3 | 27 | The User Requirements of the RU tank have properly defined the mixing needs based on the characteristics of the colloidal system.<br>The initial evaluation and information sharing between SU, RU and the disposable technology Supplier have identified the appropriate mixing device.<br>The PQ challenge of the mixing system will include appropriate tests suggested by the supplier/owner of the technology |
| | | Density | Temperature of the system out of range specified by the SU | 2 | 1 | 1 | 2 | *No further action needed.* The colloidal system is not sensitive to temperature. The RU WFI loop cooling and temperature control system will guarantee a 15-25°C range. |
| | | | Sampling mode device impact on the analysis results | 3 | 2 | 2 | 12 | The sampling system will be made of pharmaceutical grade glass. The SU have collected data on compatibility and the solution is declared compatible with glass devices. |
| | | Sterility | Preparation time impact on bioburden level of the final compounded solution | 3 | 2 | 2 | 12 | Validation activities will include hold time challenges according to a dedicated protocol.<br>Chemical characteristics and microbiological attributes of the solution will be analyzed. |
| | | Particulate matter | Particle release from disposable hoses may impact the particulate matter profile | 3 | 2 | 3 | 18 | Use Silicon, Pt-cured, disposable hose certified for pharmaceutical use for solution transfer.<br>To address particle release from the hoses used in Grade C, filter the solution 3 times before filling (0.45 um + 0.22/0.2 um in grade C area and 0.22/0.2 um in grade A area).<br>Regarding the particle release from the hoses used on the filling machine, a final 100% visual inspection will be done. Vials with a particle matter defect will be rejected. |

# Technology Transfer - Risk Management

| Analysis | | | | Risk Priority Number Evaluation | | | | Mitigation Plan |
|---|---|---|---|---|---|---|---|---|
| Item | Variable | QA Impacted | Potential criticality/cause of lack of quality attribute description | Severity | Occurrence | Detection | RPN | Consideration / Action |
| Process | Mixing and compounding | pH | Dissolution speed is insufficient for complete dissolution and a homogenous system. | 3 | 3 | 1 | 9 | During the performance qualification, the mixing device of the tank used in the RU will be challenged. Mixing studies will be agreed on by the SU and performed during the engineering batch. |
| | | Osmolality | Dissolution speed is insufficient for complete dissolution and a homogenous system. | 3 | 3 | 1 | 9 | |
| | | Appearance | Mixing system is not appropriate to guarantee uniform batch mixing | 3 | 3 | 3 | 27 | The user requirements of the RU tank have properly defined the mixing needs based on the characteristics of the colloidal system. The initial evaluation and information sharing between SU, RU, and the disposable technology Supplier have identified the appropriate mixing device. The PQ challenge of the mixing system will include appropriate tests suggested by the supplier/ owner of the technology |
| | | Density | Temperature of the system is outside the range specified by the SU | 2 | 1 | 1 | 2 | No further action needed. The colloidal system is not sensitive to temperature. The RU WFI loop cooling and temperature control system will guarantee a 15-25°C range. |
| | | | Sampling mode device can affect the analysis | 3 | 2 | 2 | 12 | The sampling system will be made of pharmaceutical-grade glass. The SU has collected data on compatibility, and the solution is declared compatible with glass devices. |
| | | Sterility | Preparation time can affect the bioburden level of the final compounded solution | 3 | 2 | 2 | 12 | Validation activities will include hold time challenges according to a dedicated protocol. Chemical characteristics and microbiological attributes of the solution will be analyzed. |
| | | Particulate matter | Particles release from disposable hoses may impact the particulate matter profile | 3 | 2 | 3 | 18 | Use Silicon, platinum-cured, disposable hose certified for pharmaceutical use for solution transfer. To address particle release from the hoses used in grade C, filter the solution three times before filling (0.45 um + 0.22/0.2 um in grade C area and 0.22/0.2 um in grade A area). Regarding the particle release from the hoses used on the filling machine, a final 100% visual inspection will be done. Vials with a particle matter defect will be rejected. |
| | | | Mixing system shedding may impact the particulate matter profile | 3 | 2 | 3 | 18 | Supplier has provided leachable/ extractable documentation and certifications. Compatibility studies to be conducted with specified analytical methods with the supplier. |

# TT IG – Goals for 2017


- Through a ***Team Survey*** in 2016 - Key Goals were identified.

- In 2016 & 2017 the team worked on the "***Regulatory Framework of a Technology Transfer***" focusing on guidance, process steps, deliverables and readiness for inspections.

  - A ***TT Matrix*** for Commercial to Commercial TT was created and currently under team review.
    - *TT Matrix was presented during last Annual Meeting (Sept 2017)*
    - Potential to publish in PDA Journal through a series of articles
    - Looking for volunteers
    - ***Next steps*** - Scope extension on Development to Commercial TT and on specific analysis in case of API and Biologics environment.

# TT IG – Next steps

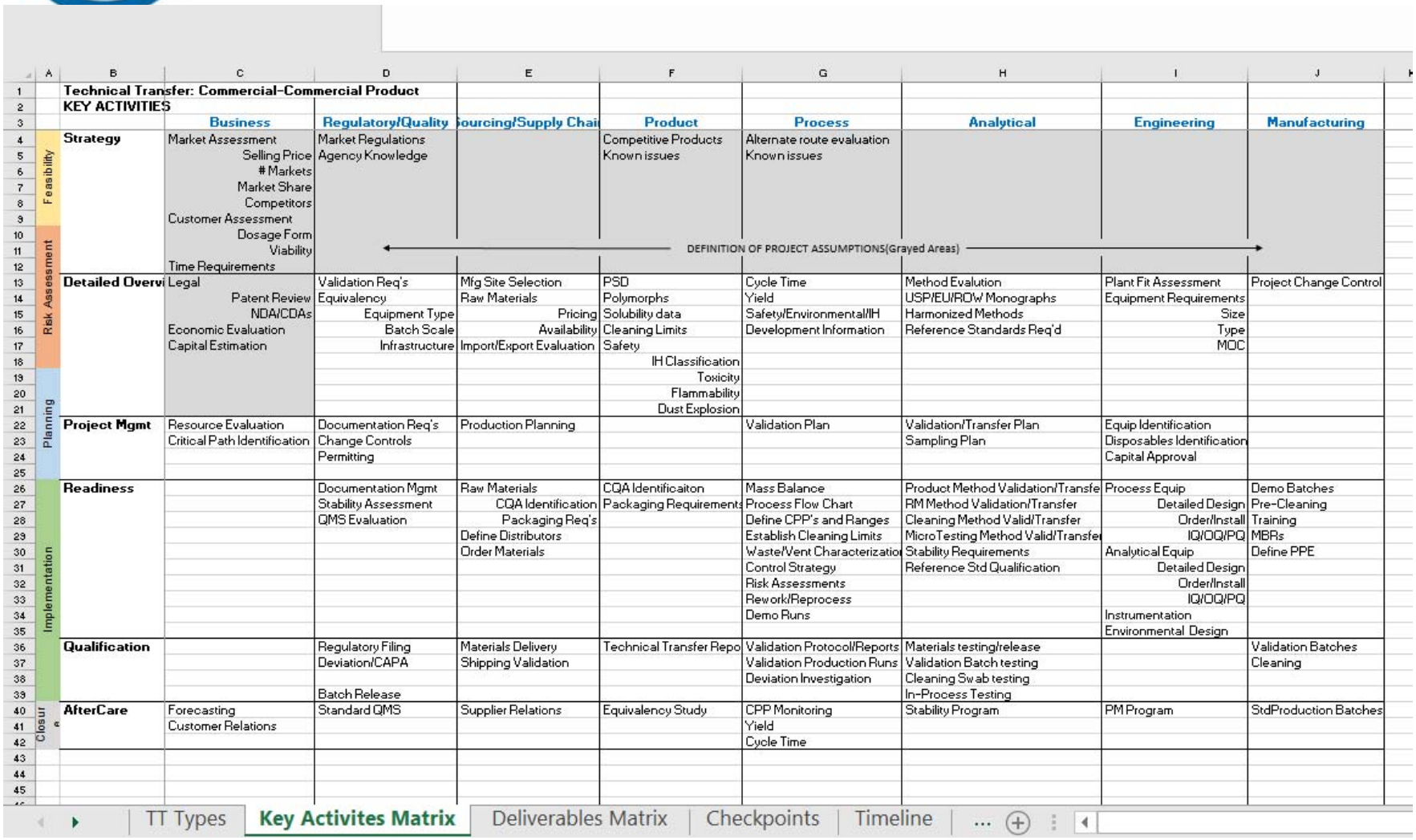
- Finalize the TT matrix review based on the TT meeting participation at the PDA-FDA mtg in Sept. 2017 ***March 2018***
- Get professional formatting of the product **April 2018**
- Do a write-up of the product on its purpose and use. ***May 2018***
- TT Matrix ed 01 (Commercial to Commercial) ready to go!


- Define next ed (*Clinical to Commercial ? – Bio vs small molecules ? – virtual company vs branded ?)*

# TT Matrix Overview

- Technical Transfer Types with Risk Categories
  - *Cumulative risk assessment to drive requisite rigor*
- Analysis of TT steps and responsibilities by:
  - *Project phase and functional group*
  - *Deliverables*
  - *Sets grouped by intersection of phase and function*
- Potential Uses
  - *TT Lifecycle Checkpoints*
  - *Benchmarking*
  - *TT Process Build up in the company*
  - *TT Checklist for Inspection readiness*
  - *Lesson learned tool and Continuous improvements of your process*

# TT Matrix Overview



**Technical Transfer: Commercial–Commercial Product**

**KEY ACTIVITIES**

| | | Business | Regulatory/Quality | Sourcing/Supply Chai | Product | Process | Analytical | Engineering | Manufacturing |
|---|---|---|---|---|---|---|---|---|---|
| **Strategy** | Feasibility | Market Assessment<br>Selling Price<br># Markets<br>Market Share<br>Competitors<br>Customer Assessment<br>Dosage Form<br>Viability<br>Time Requirements | Market Regulations<br>Agency Knowledge | | Competitive Products<br>Known issues | Alternate route evaluation<br>Known issues | | | |
| | | ← DEFINITION OF PROJECT ASSUMPTIONS(Grayed Areas) → | | | | | | | |
| **Detailed Overvi** | Risk Assessment | Legal<br>Patent Review<br>NDA/CDAs<br>Economic Evaluation<br>Capital Estimation | Validation Req's<br>Equivalency<br>Equipment Type<br>Batch Scale<br>Infrastructure | Mfg Site Selection<br>Raw Materials<br>Pricing<br>Availability<br>Import/Export Evaluation | PSD<br>Polymorphs<br>Solubility data<br>Cleaning Limits<br>Safety<br>IH Classification<br>Toxicity<br>Flammability<br>Dust Explosion | Cycle Time<br>Yield<br>Safety/Environmental/IH<br>Development Information | Method Evalution<br>USP/EU/ROW Monographs<br>Harmonized Methods<br>Reference Standards Req'd | Plant Fit Assessment<br>Equipment Requirements<br>Size<br>Type<br>MOC | Project Change Control |
| **Project Mgmt** | Planning | Resource Evaluation<br>Critical Path Identification | Documentation Req's<br>Change Controls<br>Permitting | Production Planning | | Validation Plan | Validation/Transfer Plan<br>Sampling Plan | Equip Identification<br>Disposables Identification<br>Capital Approval | |
| **Readiness** | Implementation | | Documentation Mgmt<br>Stability Assessment<br>QMS Evaluation | Raw Materials<br>CQA Identification<br>Packaging Req's<br>Define Distributors<br>Order Materials | CQA Identificaiton<br>Packaging Requirements | Mass Balance<br>Process Flow Chart<br>Define CPP's and Ranges<br>Establish Cleaning Limits<br>Waste/Vent Characterizatio<br>Control Strategy<br>Risk Assessments<br>Rework/Reprocess<br>Demo Runs | Product Method Validation/Transfe<br>RM Method Validation/Transfer<br>Cleaning Method Valid/Transfer<br>MicroTesting Method Valid/Transfe<br>Stability Requirements<br>Reference Std Qualification | Process Equip<br>Detailed Design<br>Order/Install<br>IQ/OQ/PQ<br>Analytical Equip<br>Detailed Design<br>Order/Install<br>IQ/OQ/PQ<br>Instrumentation<br>Environmental Design | Demo Batches<br>Pre-Cleaning<br>Training<br>MBRs<br>Define PPE |
| **Qualification** | | | Regulatory Filing<br>Deviation/CAPA<br>Batch Release | Materials Delivery<br>Shipping Validation | Technical Transfer Repo | Validation Protocol/Reports<br>Validation Production Runs<br>Deviation Investigation | Materials testing/release<br>Validation Batch testing<br>Cleaning Swab testing<br>In-Process Testing | | Validation Batches<br>Cleaning |
| **AfterCare** | Closure | Forecasting<br>Customer Relations | Standard QMS | Supplier Relations | Equivalency Study | CPP Monitoring<br>Yield<br>Cycle Time | Stability Program | PM Program | StdProduction Batches |

TT Types | **Key Activites Matrix** | Deliverables Matrix | Checkpoints | Timeline | ...

# TT Matrix Overview

| | | Business | Regulatory/Quality | Sourcing/Supply Chai | Product | Process | Analytical | Engineering | Manufacturing |
|---|---|---|---|---|---|---|---|---|---|
| Technical Transfer: Commercial–Commercial Product | | | | | | | | | |
| KEY DELIVERABLES | | | | | | | | | |
| Feasibility | Strategy | | | | | Feasibility Report<br>VUCA | | | |
| Risk Assessmer | | | | | | Checkpoint 1 (Project Viability decision) | | | |
| | Detailed Overv | Business Strategy | Regulatory Strategy<br>Filing Type<br>Stability Plan | Site Selection Decision<br>RM Sourcing Report | | Sending Tech Transfer Package<br>Overall Risk Assessment | | Plant Fit Assessment | Project Change Control |
| Planning | | | | Checkpoint 2 (Launch decision) | | | | | |
| | Project Mgmt | Project Charter<br>TT Master Plan | Documentation Master Lis<br>Permitting | Plant Window | Development Report | Validation Master Plan<br>Cleaning Master Plan<br>TT Protocol | Method Validation Master Plan | Plant Design Report<br>CAR | EHS Risk Assessment |
| | | | | Checkpoint 3 (Knowledge Transfer Status) | | | | | |
| Implementation | Readiness | | Documentation Mgmt<br>Stability Plan<br>Change Controls<br>Deviation/CAPA | Raw Materials<br>Specifications<br>RM Packaging Specs<br>SAP Setup<br>Supplier POs | Specification<br>Packaging Specification | Detailed Process Report<br>Criticality Report<br>Validation Protocols<br>Cleaning Protocols | Product Method Valid Protocol/Report<br>RM Method Valid Protocol/Report<br>Cleaning Method Valid Protocol/Repor<br>Micro Method Valid Protocol/Report<br>Stability Protocol<br>Reference Std Qualification | Process Equip<br>IQ/OQ/PQ Protocols/Report<br>Design Specs<br>Environmental Design<br>Analytical Equip<br>IQ/OQ/PQ Protocols/Report<br>Design Specs<br>P&IDs | Master Batch Record<br>Cleaning Batch Record<br>Training Documentation<br>SOPs<br>Pre-Cleaning Record |
| | | | | Checkpoint 4 (Validation readiness decision) | | | | | |
| | Qualification | | Regulatory Filing<br>Materials Release<br>Deviation/CAPA<br>Batch Release<br>Expiry Date | Supply Chain Map<br>Shipping Valid Protocol | Technical Transfer Repo | Validation Report<br>Cleaning Valid Reports<br>Deviation Closures | Materials testing results<br>Validation Batch test results<br>Cleaning test results<br>In-Process Testing | | Completed Batch Records<br>Completed Cleaning Batch Records |
| | | | | Checkpoint 5 (Final Project Review) | | | | | |
| Closure | AfterCare | Short/Long term plans<br>Marketing Plan<br>Customer Contracts | Regulatory Approval<br>Standard QMS SOPs<br>Complaints/Recalls<br>Quality Risk Assessment | Supply Contracts<br>Quality Agreements | | Quarterly Review | Stability Program/Report | PM Program | |

# TT IG – AoB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