**Workshop C – Outputs Summary**

**Technology Transfer and Maintenance of Dynamic Process Risk Assessments**

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| **Topic** | **Technology Transfer** | **Maintenance of Dynamic Risk Assessments** |
| **Commonalities/Areas of Consistent Practice and Understanding**  (Remember common practice is not necessarily best practice) | * Use QRM to ensure regulatory obligations are met and product quality is maintained during transfer activities * Use QRM to capture knowledge * Use of QRM to assess the impact of any changes introduced by the technology transfer and ensure mitigations are planned for identified risks and gaps are closed (although some challenged that change management was the primary vehicle for this) * Involvement of both the sending and receiving units and the use of cross functional teams with clear responsibilities & expectations * Work to create a clear scope of work with supporting schedule, train as necessary * Seek to manage subjectivity via an experienced facilitator | * All agree that we should use triggers within the deviation and change control systems to prompt updates to risk assessments when required * Use data gained from process experience and incorporate this new knowledge * Agree that we should use a mix of experienced people and new people (fresh eyes/other company perspective) |
| **Differences in the application of QRM** | * Differences in how actions highlighted during the technology transfer are managed e.g., some use a CAPA system, others use risk registers, others use project management tools etc. * Different tools used to perform the assessments and evaluations required by the technology transfer * Different levels of detail for the technology transfer processes – how much of a deep dive (varied within company for different transfers also) | * Risk registers – variation in their format, use and formality. Often used as a more informal or project management tool, and sometimes there are differences between sites. * How we use data from deviation and change management system and feed it into risk assessments * Range of tools used |
| **Challenging Areas to Interpret/Apply** | * Third party transfers pose more of a challenge * Knowledge management – in particular the flow of tacit knowledge – how to do this? * Lack of transparency at receiving site – difficulty identifying gaps if sites do things that are not detailed in procedures * Communication can be a challenge – how to effectively communicate and to the right level * Material and equipment is pretty straightforward; people and lab capability is a ‘black box’ and risky * Dependency on people behaviors (link to Nuala presentation) * Inappropriate use of QRM as a get out of jail card! * “politics” * Making the tech transfer risk assessment a living document | * How to integrate QRM into the deviation and change management systems effectively * Risk review – different interpretations on what periodic review entails and how it should be performed |
| **Areas for Future Discussion/Research** | * Risk as everyone’s responsibility * Training people in local risks (reporting & capturing) * Managing subjectivity * Recognizing link between knowledge & risk / application of RKI cycle * Risk communication - Understanding one’s audience and communicating effectively and often * How to make the technology transfer risk assessment a living document | * How to execute periodic review – existing quality systems that can be used as opposed to re-inventing the wheel and to avoid the error of simply re-executing the risk assessment * Understanding the benefits of an effective periodic review (continuous improvement) * How to effectively make risk assessments living documents (periodic and event driven risk reviews) * Tools to remove subjectivity during risk assessments e.g., private voting systems such as Spiro to gather silent feedback * Risk register – How to make this more effective and impactful. * Bigger teams (ensuring the right people) * “Knowledge management is key” * Widen SMEs; reflection on the type of SME and level of formality * Application of AI & ML – will introduce uncertainty (per Val presentation) – need to help people with the right mindsets to navigate this |