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The films are an effective communication and training tool because, aside from the expert commentary, they explicitly show the correct actions that personnel must follow in order to be compliant with Good Manufacturing Practices and internal procedures.

Due to the effectiveness and efficiency achieved with the videos, the site is considering developing similar videos for warehouse operations that would include fractioning and lot preparation, sample receipt, sampling and stocking.

Still-shots from the GLP video, The Analysis Laboratory – PGM Ascoli Team R to L: (from top to bottom) Tommaso Volpicella (Quality Operations Manager), Orenzo Agostini (GMP Training Manager), Luciano Lori (Laboratory Assistant), Daniela Tomassini (Laboratory Analyst), Daniela Pompei (QC Laboratory MDI), Giovanni Granno (Chemical Laboratory Manager) and Gianluca Paniccia (Quality Control Manager)



GLP: The Analysis Laboratory

## Quality Connections The Quality Risk Management 10-Step Process Facilitation Tool

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**B**oth industry and regulators are highly interested in the appropriate use of science and risk around the world. They are seeking enhanced decision making in the industry by taking into account the level of risk that actions and processes entail. The goal is to ensure that patients are protected, while innovation (the keystone to improved outcomes) is not stifled by over-prescriptive regulation. The idea has been codified in ICH Q9, *Quality Risk Management*, and Pfizer has been at the forefront of this initiative, encouraging development of such a Quality culture in everything we do.

Over the last three years, a team of extraordinary Pfizer colleagues has joined forces in the Quality Risk Management Network. This network is a venue to provide Quality Risk Management education, gather ideas, foster discussion and develop a process that uses such a risk-based, scientific approach to reach decisions supported by data and driven by good science.

The result has been the development of a scientifically rigorous yet flexible Quality Risk Management (QRM) process. The process uses 10 defined, separate, sequential steps that lead teams involved in complex issues to reach sound, valid decisions. Its beauty lies in the fact that it fosters consistency across users, whether the issue is best solved by the use of Failure Mode and Effects Analysis (FMEA), Risk Ranking and Filtering (RRF), or any one of the many other tools in the ICH Q9 toolbox. The emphasis is first and foremost on the safety of patients, while ensuring that compliance, regulatory and business issues are taken into account. The complexity of the tool used and the extent of documentation are dependent upon the complexity of the evaluated issue.

To ensure this enhanced Quality culture becomes a part of everyone's daily thoughts and actions, the Quality Systems Support Team led an initiative to develop a program to train colleagues in the elements of QRM. The strategy included

presentations and workshops at various sites and for specific situations, individual assistance from QRM network members by email, telephone, NetMeeting and through facilitated visits to implement the process.

After using the 10 Step QRM process for some time, it became evident that a helpful access would be an easy to fill out form that would aid in documenting each of the QRM process steps on a consistent basis, no matter what tool was being used to manage the risk. This led to the development of an automated job-aid that would not only document the process, but would guide teams through the process, perform calculations, and suggest which hazards and mitigation based on the risk profile developed by the QRM teams. The tool is Excel based, hosted in the QRM Sharepoint site and can be accessed by all Pfizer colleagues. For data acquisition, supported by links to Visio-based template Fishbone Diagrams and Flow Charts, as well as Excel-based Pareto and Run Charts, although

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