

**SUPPLIERS
SELECTION
AND
ASSESSMENT**

**RISK ANALYSIS
GOES LEAN**

SUPPLIERS ASSESSMENT: WHY?

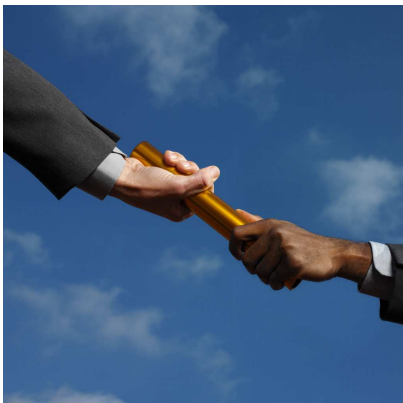
It is a matter of survival for Companies the need to select Qualified Suppliers at reasonable costs, pursuing an unstable equilibrium between Reliable Quality and Expenses that can be borne.

Unlike other industrial sectors, the Pharmaceutical Industry cannot take advantage of techniques as “specifications optimization” or “margin of safety standardization”. The Product Specifications ARE the Product: they cannot be changed, unless the product is substituted.

For this reason, Quality Assurance has achieved absolute greatness in *Life-Sciences* sectors. For the same reason, a combination between the better Quality instruments (*Risk Analysis*) and means for waste identification (*Lean*), applied to procurement processes, can help to achieve good results: so, industrial systems of great experience can stand more and more difficult competitions.

CTP SYSTEM's suggestion:

- ***A posteriori* method in order to assess Suppliers, starting from historical data, and obtain a Matrix for an efficient Audit Management**
- ***A priori* approach for effectively managing Selection or introduction of new partners**





SCOPE

To seize the opportunity offered by Risk Analysis integrated with a process of Suppliers Assessment / Selection and supported by Lean-Tools.

- Materials
 - Assessment of use Criticality (product and process)
 - Assessment of use Significance
 - Assessment of Analytical History (Trend Analysis)
- Suppliers
 - Assessment of Reliability and Consistency
 - Assessment of Strategicity and Interchangeability
- Tools
 - Risk Analysis (FMEA, HACCP)
 - Scoring and Performance Indicator
 - Inter-functional Audits
 - Business Continuity Matrix

PRELIMINARY ACTIVITIES

- To make a study of all the used suppliers, as for active principles, excipients and packaging materials, in order to optimize Qualification Activities:
 - Approved Suppliers List
 - Compliance & Criticality
 - Supplier Quality Scoring
 - Process Capability
 - CAPA Programs

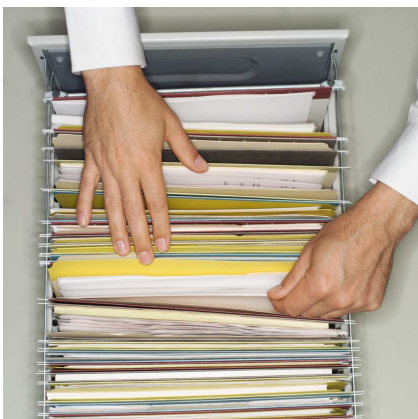
- To set up a Risk Analysis oriented to Suppliers classification into criticality classes related to production processes
- To choose the technique, define and analyze dangers, calculate risks and assess results
- To issue Risk Assessment Report including Action Plan
- To define necessary activities for Suppliers Qualification

After having obtained RPN from RA and set Suppliers in specific criticality classes, qualification activities will be defined through distribution analyses, according to these criteria:

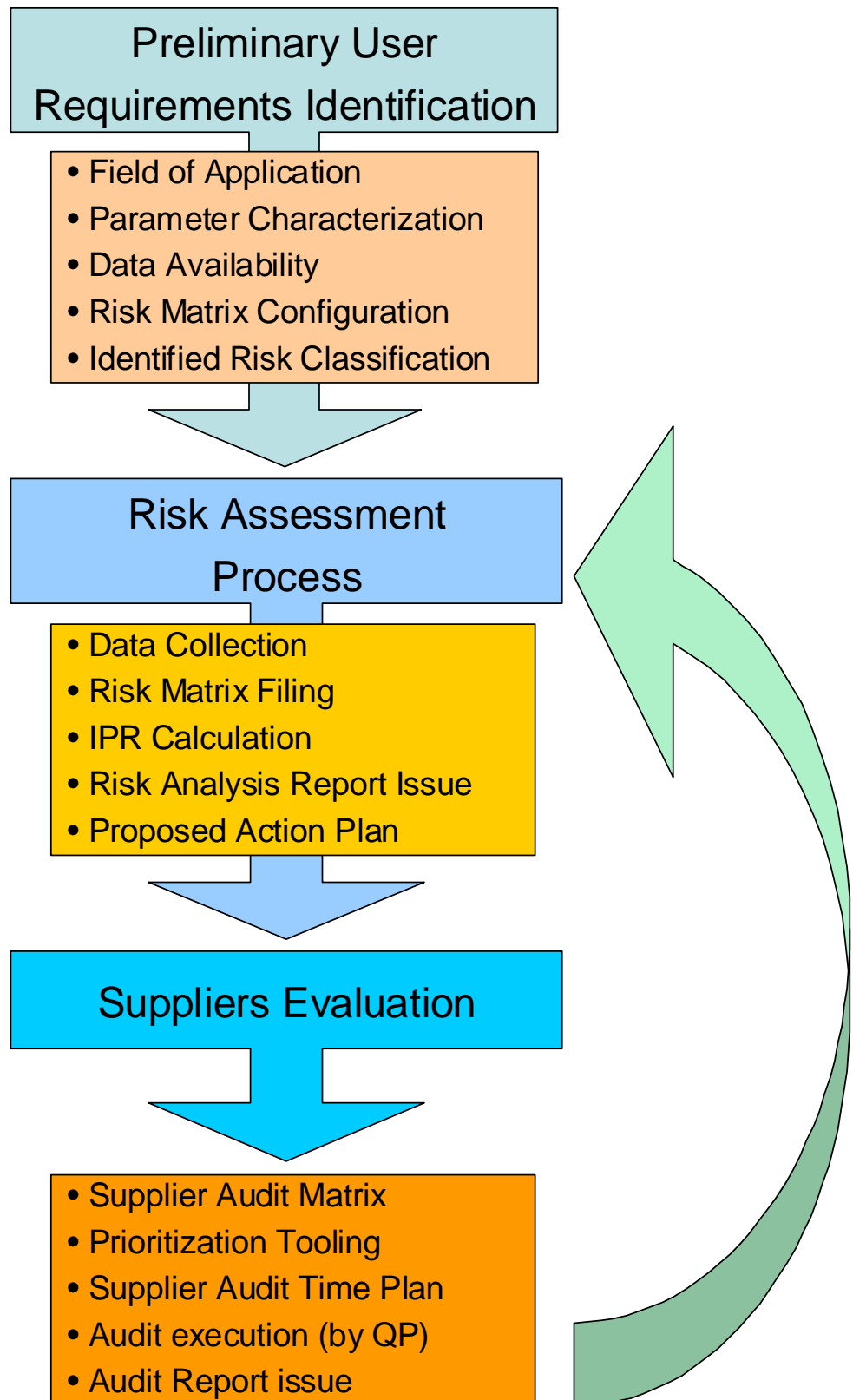
- *Volumes Parameters* (Turnover, # Deliveries)
- *Procurement Strategy* (Local vs. Central)
- *Business Continuity Risk* (No-Delivery Probability)
- *Supplier Performance Index* (Price, Quality, Delivery, Expertise and Relationship)
- *Internal Sourcing Evaluation* (Single vs. Multi)
- *External Sourcing Evaluation* (Stocks and components, Market situation)

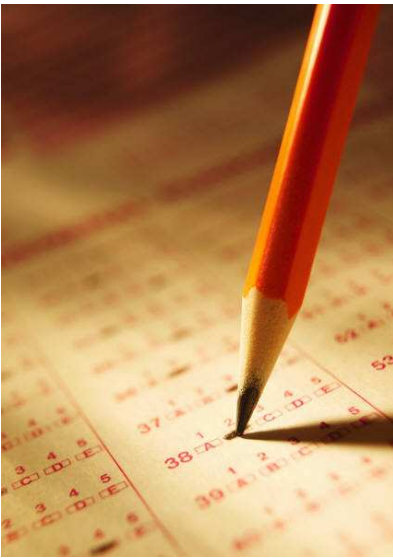
The result will be the issue of a Risk Assessment for defining a Supplier Audit Matrix, supported by great logic in Audit planning, because it is based on the use of standardized Tools.

CTP SYSTEM offers itself also for fully manage the subsequent phase of verification and control, with Audits performed by QP, from planning to Reports issue and follow-up of corrective actions.



FLOW CHART





EXAMPLE OF CRITICALITY CLASSIFICATION

We report as an example a list of criticality classes that could be defined for Suppliers:

- *CLASS A - High Criticality* - Annual Audits; statistical test of analytical data for every batch of product received; analytical identification for every unit of product sent; execution of pharmacopoeia monograph and/or specific customized tests every 5 batches; etc.
- *CLASS B - Medium Criticality* - Biennial Audits; statistical test of analytical data for every batch of product received; analytical identification for every unit of product sent; execution of pharmacopoeia monograph every 10 batches; etc.
- *CLASS C - Low Criticality* - Triennial Audits through sending/receiving a specific check-list; reduced statistical test on future batches; execution of pharmacopoeia trials every 10 batches received; etc.

If the class distribution point out a too high level of complexity, it would be necessary to use other screening criteria:

- Volumes parameters (arrivals / shipments)
- Internal strategies / Market situations
- Risk Assessment of Business Interruption
- Index of Global Assessment of Suppliers



ATTAINABLE OBJECTIVES

- **Qualitative:**

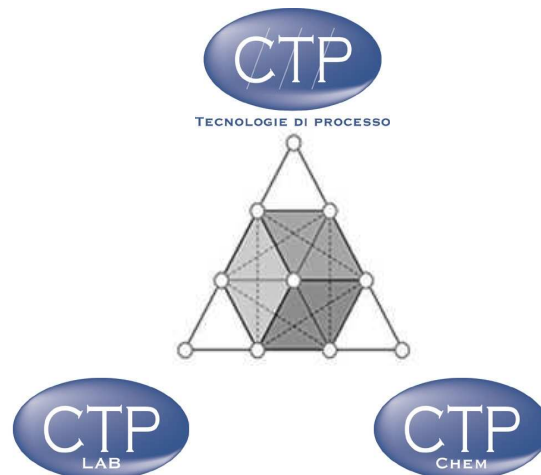
Audits more effective (*less for more*), efficient (multi-disciplinary Teams) and standardized (integration with database of PQR / APR).

- **Operating:**

Process of Suppliers selection more rational (common *modus operandi* for better sharing information) in order to allocate or free resources, and speed up improvement processes for introducing new suppliers / materials / components.

- **Financial:**

Additional charges optimized, reducing complexity costs and maximizing the Benchmark at a Corporate level.



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