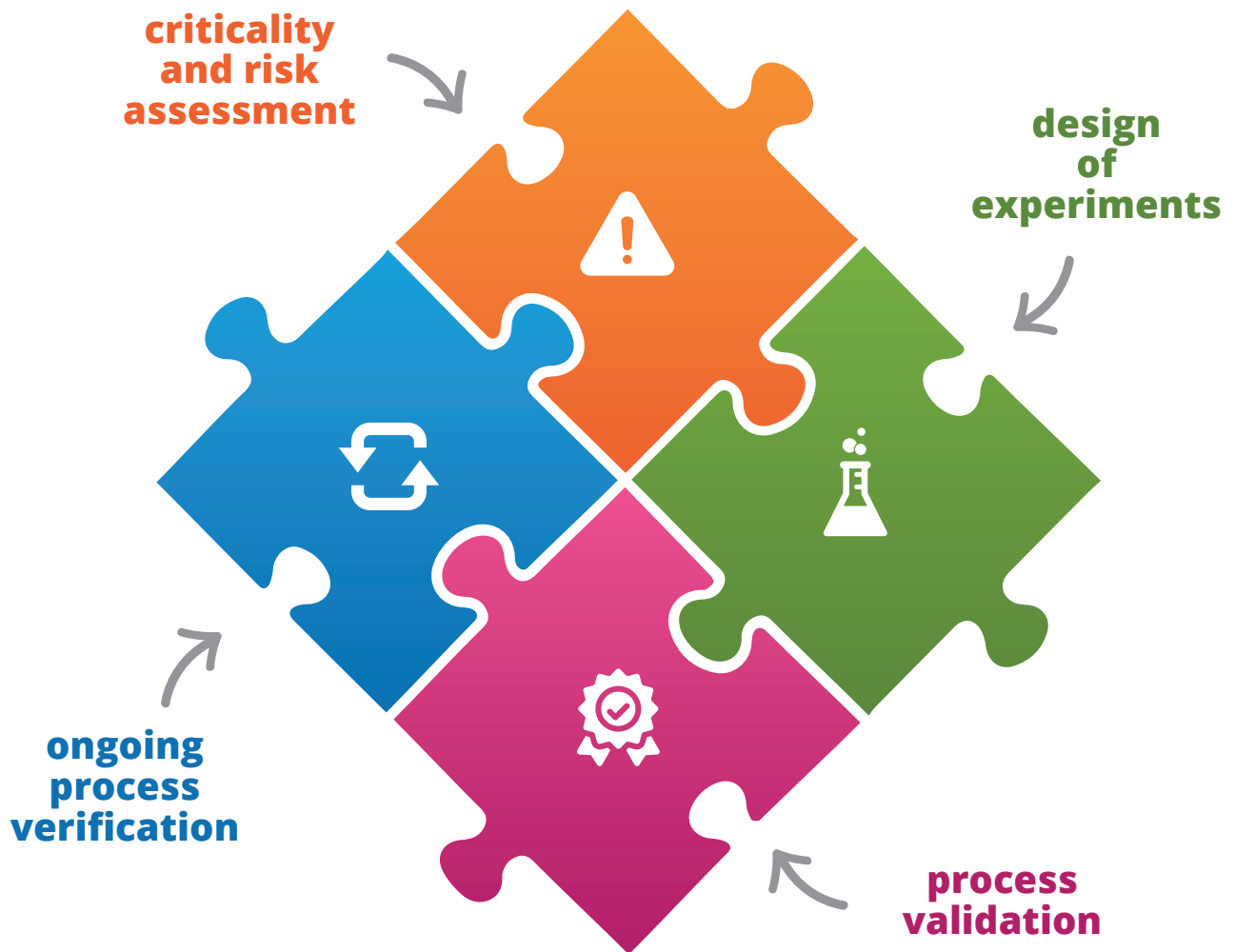


# QbD LIFE CYCLE



StatSoft offers a system that enables the collection, analysis, storage and sharing of data related to products, manufacturing processes and components throughout the product lifecycle according to Annex 15.



# QbD LIFE CYCLE

- ✓ Merging data describing activities at all stages of the product life cycle into a single stream of information about product and process.
- ✓ Integration with the quality system.
- ✓ Continuous improvement of process performance and product quality by identification and control of sources of variation and causes of defective product.
- ✓ Standardization of technological process development based on the QbD methodology.
- ✓ Evaluation of criticality of quality attributes, process parameters and risk of occurrence of OOS results for product attributes based on knowledge gained and experimental data.
- ✓ Ongoing real-time verification of the process with identification of atypical trends and OOT/OOS results.
- ✓ Visualization of the process monitoring results in real time for persons involved in releasing the product on the market (e.g. Qualified Person).
- ✓ Generation of automatic notifications and OOT/OOS alerts for persons involved in the release of the product on the market.
- ✓ Monitoring of quality indicators (OOS/OOT, Cpk) and technological indicators (production waste, time of technological operations).
- ✓ Integrated portal that enables a holistic view of process performance and product quality throughout the product lifecycle from development to commercial manufacturing.

# FOR WHOM?

- For research and development departments to implement the QbD approach easily
- For quality assurance departments to monitor the process in real time and detect atypical trends
- For technological departments to increase effectiveness of medicinal products manufacturing



# CONTACT US!



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