www.qualitybydesign.es

Scientific & Risk Based Compliance

QbD Pharmaceutical Services S.L

About us

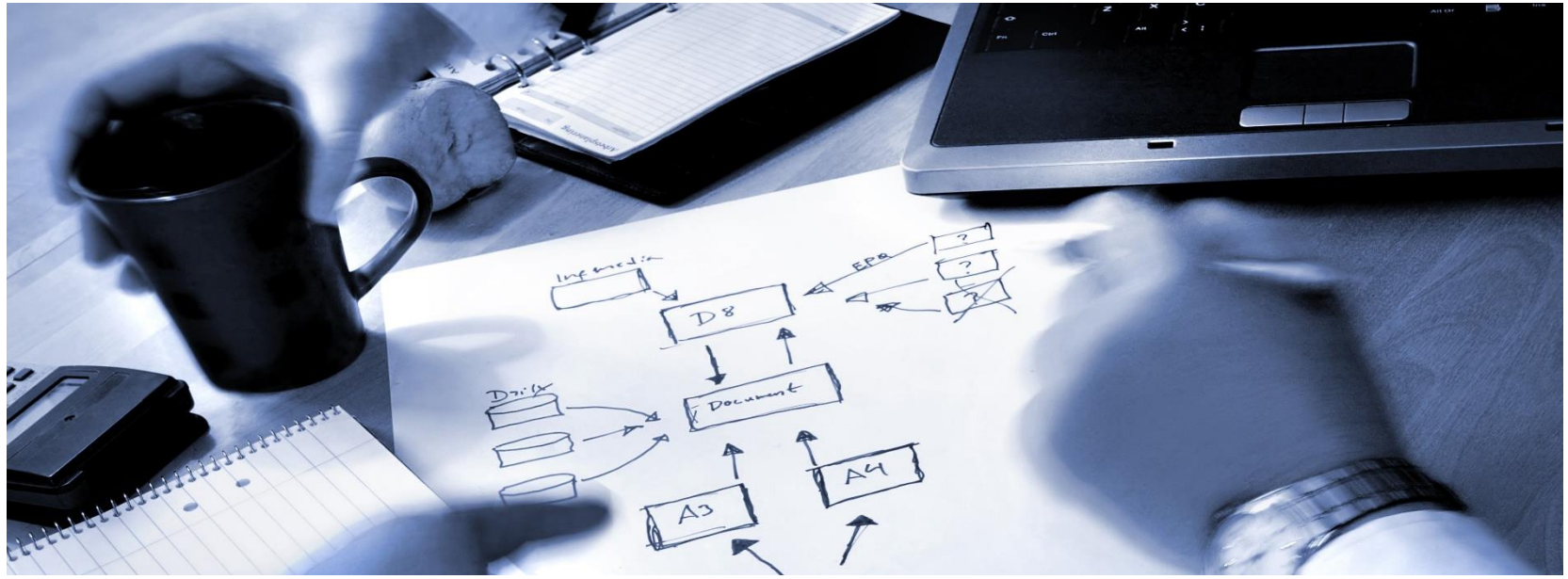
- QbD Pharmaceutical Services S.L delivers high added-value services and specialised outsourcing solutions to pharmaceutical and biopharmaceutical companies.

Mission

- QbD provides staff with the specific skills, project management abilities and extensive knowledge of Pharma regulations that you need to succeed with your projects.

Flexibility

- Providing external resources to specific and temporary needs, as deployment of new projects or implementations of new regulations in a very flexible manner, can be a good solution for your company.



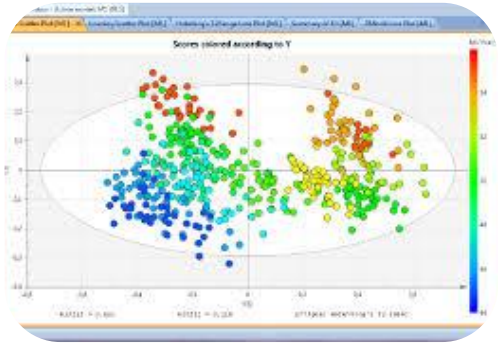
Our references

Seasoned consultancy team (15-20 years experience in pharma)
More than 100 projects delivered for 40 different companies in Europe and South-America.

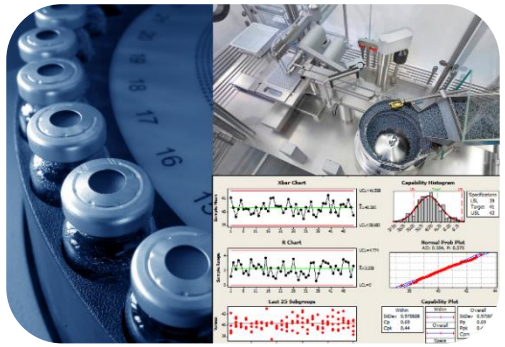
Services to cover the whole product Life-Cycle

Stage 1 & 2

Design & validation



Quality by Design. Training



Process validation

Statistics. Training

Cross contamination

Stage 3

Continuous improvement

Process improvement. Six Sigma training.

Quality Systems & Audits

Water & Energy Cost Savings

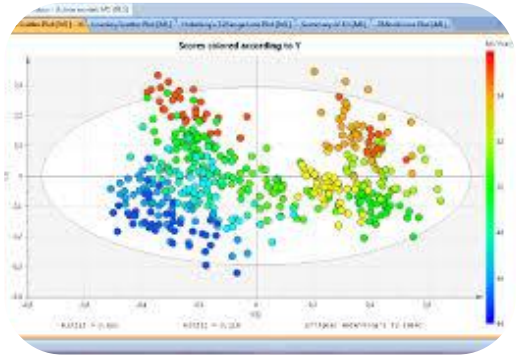
Smart QbD™

- Specific
- Measureable
- Attainable
- Relevant
- Time Based

QbD Pharmaceutical Services S.L introduces SMART QbD™, a comprehensive step-by-step methodology to assist companies in their QbD projects.
After more than 10 years providing training, advice and project management to companies in their Quality by Design journey we have designed an own methodology called SMART QbD™.

Check out SMART QBD

We partner with our clients to transform the *quality by design* concept into a concrete and tailored methodology.



Quality by Design.
Training

Process improvement.
Six Sigma training.

QbD

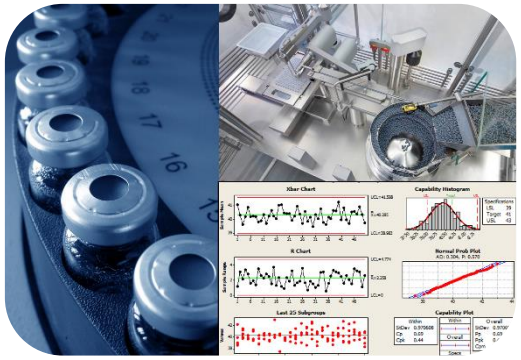
Training course

QbD (SMART) in chemical-bio-pharmaceutical development

- QTPP, CQAs, CPPs. Formulation and process design. Protocols and reports.
- Risk analysis during development, scale-up and process validation.
- Consulting, training and advice on the practical application of Design of Experiments: screening, optimization and robustness.
- We help your company with the technical writing to support the CMC part with enhanced approaches (QbD) and advanced Control Strategies..

Reverse QbD and process improvement in pharmaceutical operations. Six Sigma projects.

- We lead quality improvement and optimisation projects on legacy products.
- Our Black Belt consultant makes a previous statement of quality goals and return of investment ROI.
- We apply Six Sigma DMAIC methodology to identify root causes of low quality/performance, specially adapted to regulated industrial operations.
- Final goal is restoring stability and process capability to reduce non-conformance rates to acceptable levels.



Process validation

Supporting life-cycle activities: design, qualification and on-going verification.

-Deployment of risk analysis tools and methods for process validation. Our consultants act as facilitators and provide RA tools for the multidisciplinary team.

-Process validation documentation: Validation Master Plan, Process Validation Protocols and Reports. We have experience in oral solid forms, aseptic-sterile, biologics and cellular therapies.

-Update to new process validation guidances and ANNEX 15 EU GMPs: general procedures, design, qualification and “on-going verification” protocols and reports.

- Process state of control assessment and statistical advice.
- Critical variables to monitor.
- Exploratory Data Analysis: Data Mining.
- Statistical Process Control : SPC uni & multivariate.
- Root cause analysis and troubleshooting.

-Consulting and advice on “Process Knowledge” deployment.

Data Analysis
Statistics &
Training

Training.

- We have performed “in company” seminars and workshops on applied statistics, DoE and exploratory data analysis in more than 20 pharma European and Latin American companies.
- Tailored programs and workshops using real cases on client demand under CDA.
- We use software for practical sessions (JMP, Minitab) in a “hands-on” approach that let the assistants apply new learned skills immediately in their own projects.
- Seminars can be delivered at your site or in webinar format.

Outsourcing.

- Data Analysis is a time consuming task to be performed by qualified personnel. We can support your company in this area .
  Production data analysis: raw materials variability, data historian studies for PQRs or to define “on going verification” protocols and reports, stability studies, analytical method validation, process validation, root cause analysis for troubleshooting……
- Design of experiments: formulation and process development, scale-up, tech-transfer and optimisation.
- Design of “process intelligence” systems oriented to PAT and CPV.

Cross contamination

EMA “Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities” has changed criteria to assess cross-contamination risks in shared facilities.

Now specific and relevant toxicological data have to be used to recalculate exposure limits, in order to define if a product can be manufactured in a shared equipment, manufacturing line or even in the same premises than others.

We offer tailored services in this area including:

Risk assessment for the introduction of a new API in an existing plant or for the re-evaluation of existing shared premises.

Toxicological reports supporting NOAEL and related data as the basis for PDE/ADE calculations. Reports are reviewed and signed by a qualified expert toxicologist.

- Update the cleaning validation policy with the toxicological criteria.
- Cleaning validation protocols and reports.
- Cleaning procedures optimisation: performance and use of water.

Quality Systems & Audits

GxP Compliance and Third Party Audits

- Implementation of Pharmaceutical Quality Systems ICH Q10 and GMP requirements updating.
- GDPs implementation. Quality Manual and procedures.
- GMP/GDP/GLP audits: Auditors with international experience. Manufacturing and control of DP, API, excipients, medical devices and food supplements. Development: CROs, bioanalysis, CMC.
- Risk analysis: Customised training and expert facilitators to lead risk analysis projects: development, validations, process etc.

FDA projects.

- GAP Analysis and report with recommendations to adapt operations to FDA requirements.
- Review of CMC documentation to fulfil Question Based Review in generic products. Adaptation to ICH Q8 / Q11 Guidances
- Review of Quality System and Quality Control operations and procedures.

Water & Energy Cost Savings

We help you to optimize water & energy consumption and to deal with environmental regulations.

Integral optimization. Economic savings opportunities. Products & Services

-Technical assessment consultancy services:

- Use and consumption of water and energy.
- Water recycling and reuse.
- Unconventional resources, rainwater harvesting and grey water reuse.

-Sampling and analysis of water and air emissions.

-Legal advice, administrative proceedings on discharge permits and limits, water rate, environmental permits. Legal defense.

-Efficiency and management of energy in factory.

Goals & ROI

-Reduction of water and energy consumption. Improve energy efficiency and water savings in industrial facilities.

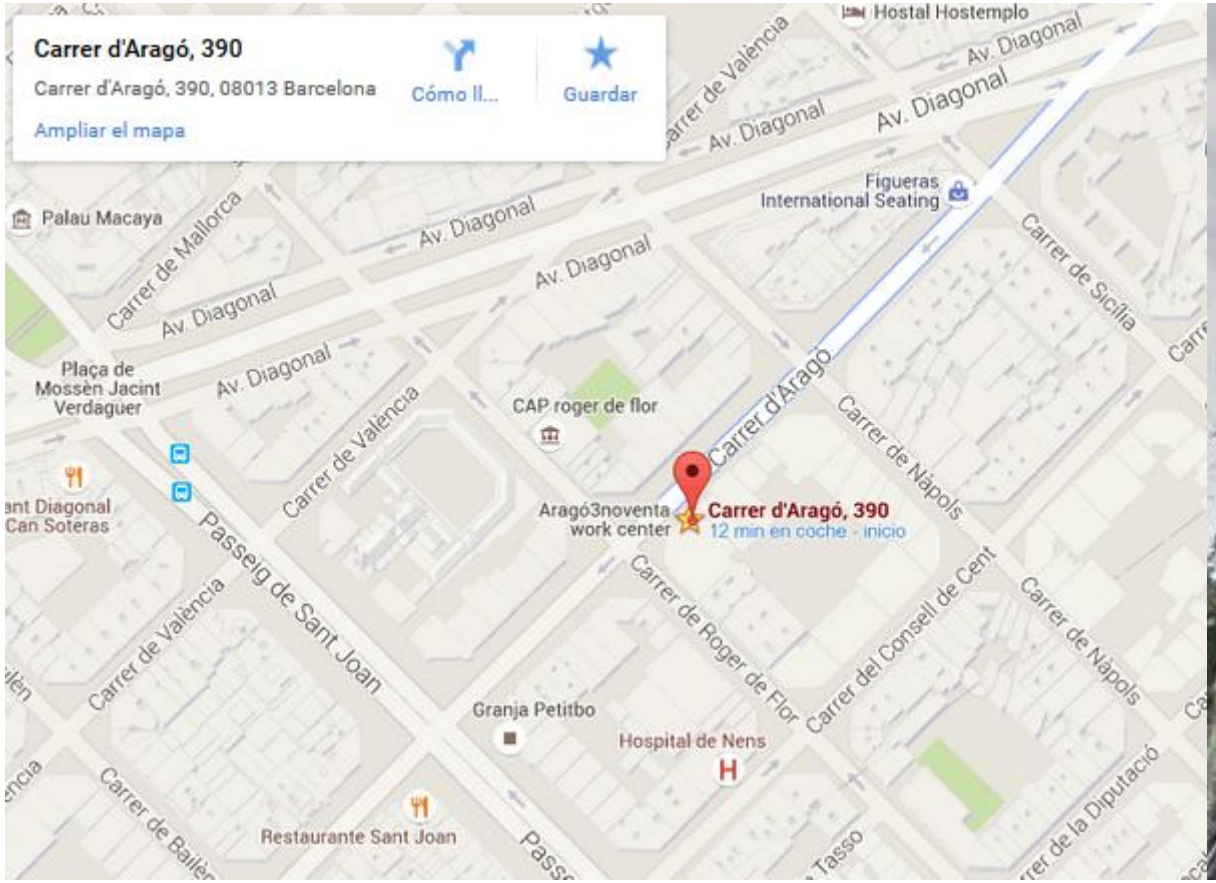
-Minimization and prevention at source of effluents, discharges, sewage sludge, industrial wastes, air emissions. Pollutant emissions control.

-Specific solutions based on BATs for the Chemical and Pharmaceutical sector.

-Economic, environmental and social sustainability:

- Reduce operating costs (OPEX) and associated taxes.
- Compliance with environmental regulations.
- Improve corporate social responsibility.

Contact Us



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