



Qualification Services



Client Benefits

Engineers with extensive hands on experience enable relevant documentation to be prepared and efficiently executed.

BPE engineers understand the systems that they are working with ensuring a comprehensive approach enabling acceptance criteria to be readily identified.

A wealth of in-house experience enables complex systems to be evaluated against historical data providing immediate results.

BPE offers a comprehensive, effective and flexible Equipment and Systems Qualification service to the Pharmaceutical Industry. Our engineers are fully conversant with the requirements of regulatory codes and guides such as the American (CFR 21 parts 210-211), British (MCA Orange Guide), European (EU GMP Guide Annex 15) and ISPE Baseline Guides. We also have substantial experience of working within the quality procedures of a number of blue chip pharmaceutical companies.

We facilitate all qualification practices, including:

- **System Impact Assessment**
- **Enhanced documentation, document management and approval process**
- **Change control**
- **End User Participation**
- **Training**
- **Use of Qualification Rationales to identify what should be checked, why, how and by whom**

BPE's engineers have a wealth of practical experience supplemented by regular training in the latest developments maintaining expertise and leadership in the field.

Experience Base

BPE engineers have worked with numerous clients accommodating our standard methods to blend with local practices.

Where requested, our cross company experience enables us to modernise local practices realising immediate efficiencies.

BPE maintains its skill base through the membership of professional bodies and participation in information exchange of latest practices.

Details

BPE has core competencies of project management, engineering design and knowledge of statutory and industry safety, health and environmental requirements. These skills are applied throughout the project lifecycle ensuring added value is delivered to all of our qualification activities.

URS. The User Requirement Specification document is written with input from the end user. BPE engineers' unique experience and understanding of both qualification and facility design / operation enables the user requirements to be easily established and documented.

VMP. The Validation Master Plan is a high level document capturing the project validation strategy. Our professional engineers have extensive knowledge and experience meaning that we are able to offer a consistent interpretation, yet flexible and innovative approach, to guide all commissioning and qualification processes.

Protocol Generation / Execution. For direct impact systems BPE have a track record of delivering a comprehensive and cost effective service including Enhanced Design Review (DQ), IQ, OQ and PQ to ensure compliance with CGMP

SOPs, Commissioning and Training With our continued success in integrating commissioning activities to support the qualification exercise we are also able to generate or update existing Standard Operating Procedures to ensure safe and compliant handover of new facilities.

For further information contact
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