

Process-/Project Planning – Engineering Healthcare

Our service ...

Bayer Technology Services – Engineering Healthcare is an experienced partner serving the pharmaceutical and biotechnology industries. We provide a background of engineering excellence, a depth of process and GMP expertise, and a wide range of services based on our three centers of competence:

- Active Pharmaceutical Ingredients,
- Formulation and Processing,
- Biological Products and Biotechnology.



Pharma Development pilot plant Wuppertal, Germany, 2002

We offer total execution of projects worldwide in all classes of GMP production:

- Process development through all phases of engineering and construction to commissioning and qualification,
- Active ingredient to filling and packaging,
- Upstream fermentation and downstream processing.

Our goal is to assure that your projects are delivered on time, on budget and as planned.

... is your gain.

We offer a full range of services to manage your investment in the healthcare industry:

- Project management,
- Feasibility and concept studies,
- Engineering,
- Construction,
- Commissioning and qualification.

Our expertise encompasses all aspects of an investment, for example:

- Pharmaceutical and biotechnology manufacture,
- Design and construction to meet all GMP cleanliness classes,
- Handling for high potency materials: docking systems, RFT transfer, etc.,
- Isolator and glove-box techniques,
- Purified water and water-for-injection systems,
- Clean-in-place (CIP) and steam-in-place (SIP) systems,
- Integrated packaging facilities,
- Commissioning and qualification,
- GMP regulations (US/FDA and EU) and other regulatory requirements.

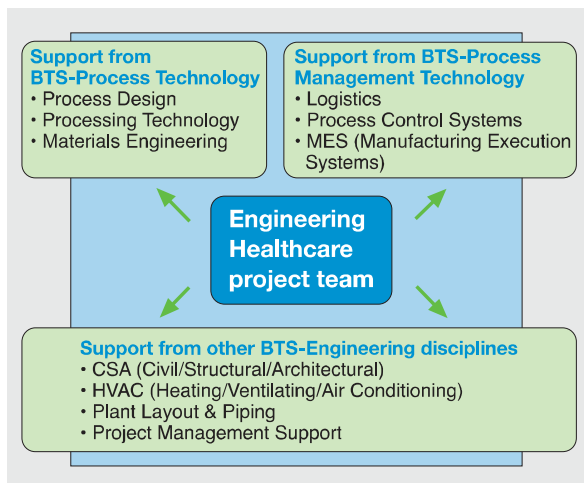


Solid Dosage Facility, Myerstown, USA, 2002



Our approach

The three divisions of BTS: Process Technology (PT), Engineering (ENG) and Process Management Technology (PMT) offer a unique and comprehensive range of expertise to our customers in the pharmaceutical and biotechnology industries. Our multidiscipline teams can draw on leading-edge technology in all areas to provide optimal solutions to your problems.



- We execute our projects using defined processes (e.g. ISO-9001 certified),
- Project-Controlling (not only limited to cost and schedule) is an integral part of the execution process,
- Well defined interfaces define the flow of information to our customers.

Our teams focus on cost effectiveness both for the initial investment and for the life cycle of the facility. Our highly motivated staff is committed to understanding and achieving project objectives and ensuring compliance with all applicable standards. All are experienced in the pharmaceutical or biotechnology industries and familiar with the issues surrounding GMP facilities:

- Many have both project and operations experience in Bayer's Healthcare businesses,
- Many have been trained in worldwide assignments through international job rotation,
- Regular training programs maintain a high skill level throughout the organization,
- Currently BTS Engineering Healthcare has groups located in Germany (Wuppertal and Leverkusen) and in the USA (Clayton, NC and Berkeley, CA).

References

Selected ongoing projects (2003):

- Active ingredient plant expansion: Wuppertal, Germany (construction),
- Biotechnology sterile filling/freeze drying facility: Berkeley, USA (construction),
- Low-volume solids plant: Bitterfeld, Germany (construction),
- New biological product facility: Clayton, USA (concept design),
- Flexibag sterile filling: Leverkusen, Germany (detail design).



Expansion of solid dose manufacturing, Lerma, Mexico, 2002

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