SPXFLOW

Anhydro Drying Systems

FOR THE PHARMACEUTICAL INDUSTRY

Anhydro®

SPX Flow Technology Danmark A/S is an international engineering company with a consistent goal to provide our customers with the optimal processing technology and the highest plant performance standards. We have specialised in supplying the optimal design and engineering with respect to production performance, flexibility, energy efficiency and environmental protection..

SPX FLOW offers a wide range of advanced Anhydro spray, spin flash and fluid bed drying technologies for handling numerous applications for pharmaceutical applications requiring maximum product integrity and reliability.

The Anhydro drying systems for the pharmaceutical industry can be combined and customised for specific product applications.

SPX FLOW also performs verification and provides complete documented quality control according to the GAMP V model.

SPX FLOW, Inc. (NYSE:FLOW) is a leading manufacturer of innovative flow technologies, many of which help define the industry standard in the market segments they serve. From its headquarters in Charlotte, North Carolina, it operates a sales and support network, centres of manufacturing excellence, and advanced engineering facilities, throughout the world. Its cutting-edge flow components and process equipment portfolio includes a wide range of pumps, valves, heat exchangers, mixers, homogenizers, separators, filters, UHT, and drying technology that meet many application needs. Its expert engineering capability also makes it a premium supplier of customized solutions and complete, turn-key packages to meet the most exacting of installation demands.

Incorporating many leading brands, SPX FLOW has a long history of serving the food and beverage, power and energy, and industrial market sectors. Its designs and engineered solutions help customers drive efficiency and productivity, increase quality and reliability, and meet the latest regulatory demands. In-depth understanding of applications and processes, state-of-the-art Innovation Centres, and advanced pilot/testing technology further assist in optimising processes and reducing timescales to reliably meet production targets.

To learn more about SPX FLOW capabilities, its latest technology innovations and complete service offerings, please visit www.spxflow.com.

Customised Drying for Pharmaceutical Applications

APPLICATION PERFORMANCE

SPX FLOW customises, builds and delivers integrated, cGMP compliant drying solutions based on a unique combination of advanced component designs, documented quality materials, precision engineering, and CFR Part 11-compliant process control and data acquisition options. These include spray drying, spin flash drying, fluid bed drying, spray bed agglomeration, and spray granulation options that comply with all current regulatory requirements.

FLUID BED - EFFICIENT AND UNIFORM MIXING AND DRYING

Fluid bed drying is used in applications requiring efficient and controlled mixing conditions and low mechanical impact on the product. Fluid beds can be equipped with nozzles for agglomeration, granulation, coating, or mixing with liquid additives. The process offers intensive contact conditions between the fluidisation gas and the product. Fines separation can be precision-controlled by widening or narrowing the upper section to achieve a specific air velocity.

Fluid bed plants can be configured in one or several sections as dryers, coolers, agglomerators, coaters or granulators. SPX FLOW supplies Anhydro fluid bed plants for both continuous and batch operation.

An Anhydro fluid bed

PLATE AND TUBULAR EVAPORATORS

In addition to drying solutions, SPX FLOW also offers falling film, rising film and forced circulation plate evaporation, and tubular evaporation plants.

SPRAY BED DRYING

Spray bed drying combines a spray dryer with an integrated fluid bed for applications with the following features:

- Good agglomeration
- Large, strong particles
- Narrow particle size distribution
- Less dust due to effective agglomeration
- Good reconstitutional properties

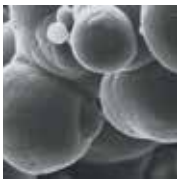
An air broom option is also available for effective cleaning of sticky products from the chamber wall. Alternatively, drying chambers can be equipped with wallsweep for removal of loose product adhering to the surface.

Typical product applications

WITH THE ANHYDRO SPRAY DRYING EQUIPMENT YOU CAN PRODUCE A WIDE RANGE OF PHARMACEUTICAL POWDERS.

Free Flowing Powders
Single-stage spray drying of APIs, excipients and final formulations into free flowing powders.

Agglomerated Powders
Spray bed drying (SBD) combines spray drying with fluidised bed technology for single-step production of agglomerated powders.



Encapsulation
For various formulations enabling special properties such as controlled release of active material.

Fine Powders
Manufacturing of very fine powder for inhalation.

Spray Congealing
Spray congealing of excipients or API with polymer.

Pharmaceutical Process Technology Options

All the Anhydro drying solutions are available as single pass systems with either ambient air or inert drying gas, or as closed circuit systems with recycling of drying gas and recovery of solvent.

SPRAY DRYING – EFFICIENT DRYING OF HEAT- SENSITIVE PRODUCTS

SPX FLOW offers spray dryer solutions with capacities starting from 1 kg/h (2.2 lb) and upwards. A sanitary and easily accessible air distribution system facilitates optimum contact between drying gas and atomized products.

ATOMIZER

The atomizer design largely determines the structure and the quality of the final powder. Spray dryers for pharmaceutical applications are often equipped with high-speed centrifugal atomizers. Other options are pressure nozzle atomization for coarser powders with narrow particle size distribution and high bulk density, and 2- or 4-fluid nozzle atomization for fine particles.

CFR PART 11-COMPLIANT PROCESS CONTROL AND DATA ACQUISITION

Anhydro drying solutions for the pharmaceutical industry feature FDA 21 CFR Part 11-compliant process control and data acquisition to accommodate individual customer requirements.

In addition to providing ultimate drying solutions, SPX FLOW also supplies cutting-edge Anhydro process control and data acquisition solutions to facilitate successful validation.

- Powerful loop and sequence control
- Access control and electronic signatures
- Secure data logging and trending
- Batch control and reporting
- Audit trail
- PAT applications
- Setpoint programmes
- Recipe management
- Alarm management
- Flexible graphics
- SVGA touchscreen display
- Validation according to the GAMP IV guidelines

The Visual Supervisor is available as a single unit for a single spray dryer or in a multiple configuration with a supervisory workstation.

Anhydro MicraSpray 150 closed cycle GMP

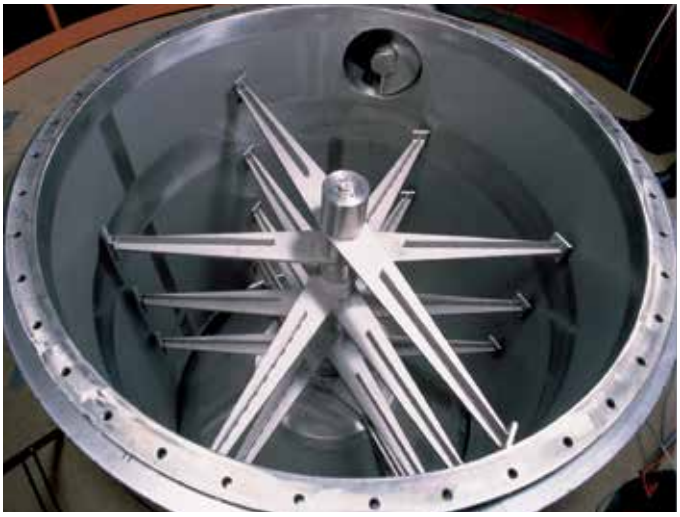
Anhydro MicraSpray 750 GMP

ANHYDRO SPIN FLASH® DRYERS– FASTER AND MORE COST-EFFICIENT DRYING

Developed and pioneered by SPX FLOW, the Anhydro Spin Flash® drying technology is a patented process used all over the world for fine powder drying applications removing the need of downstream powder milling.

Spin Flash® drying enables:

- Direct drying of high viscous pastes and slurries,
- Continuous processing with precision-controlled residence time and particle size,
- Safe drying of flammable products.



Inside view of an Anhydro Spin Flash® dryer

Global Services for Individual Needs

FLEXIBILITY AND PARTNERSHIP

For SPX FLOW flexibility is more important than standard solutions. Based on partnership, dialogue, and in-depth understanding of customer requirements, we work with your experts to define the configuration that best meets your specific needs. SPX FLOW provides experience, expertise, service and support covering all aspects of technology implementation:

- Feasibility studies
- Extensive test facilities and analytical lab
- Engineering and procurement
- Project management
- Installation and commissioning
- Qualification services
- Training and pre-production
- 24x7 service and spare parts availability
- Rebuilding and troubleshooting

SPX FLOW is committed to helping our customers all over the world to optimise product quality and plant availability, and to minimise operating costs on their Anhydro spray bed drying plants. Our solutions range from feasibility studies to full scale turnkey projects.

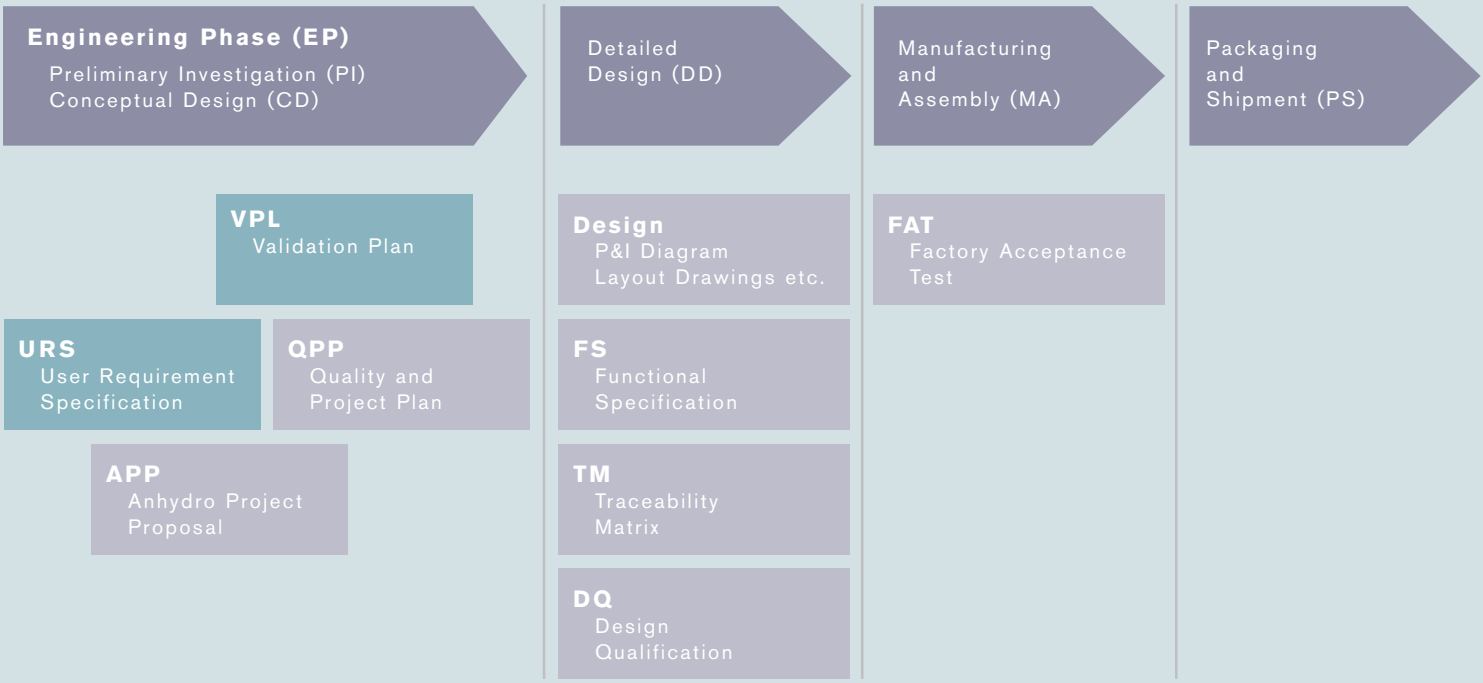
PROCESS DEVELOPMENT

SPX FLOW helps you to find the best solution for your long-term needs. We offer a close partnership based on personal commitment and documented Best Practice from the initial needs analysis and planning stage until the end of the service life of your Anhydro drying solution many years later.

Together with you we analyse the available options based on your product and throughput requirements. If required, we can run pilot tests at our innovation centre to ensure that the process will meet your expectations on a production scale.

3D computer design, global sourcing of equipment, and local manufacture, where appropriate, are part of our standard project execution.

THE ANHYDRO PHARMACEUTICAL PROJECT MODEL



SPX FLOW can assist with preparation of User Requirement Specification (URS) and Validation Plan (VPL) in the early project stages. In later project stages, we offer our Qualification Services following the ISPE Guidelines for Commissioning & Qualification.

FLEXIBILITY DOWN TO THE LAST DETAIL

Flexibility demands precision and discipline. The SPX FLOW Pharmaceutical Project Model is a detailed plan outlining a timeline for a series of detailed activities from the preliminary investigation to qualification and production. Our experts stay with you all the way, making sure that the plant is designed, configured, built and delivered to meet every single one of your specifications.

SPX FLOW INNOVATION CENTER

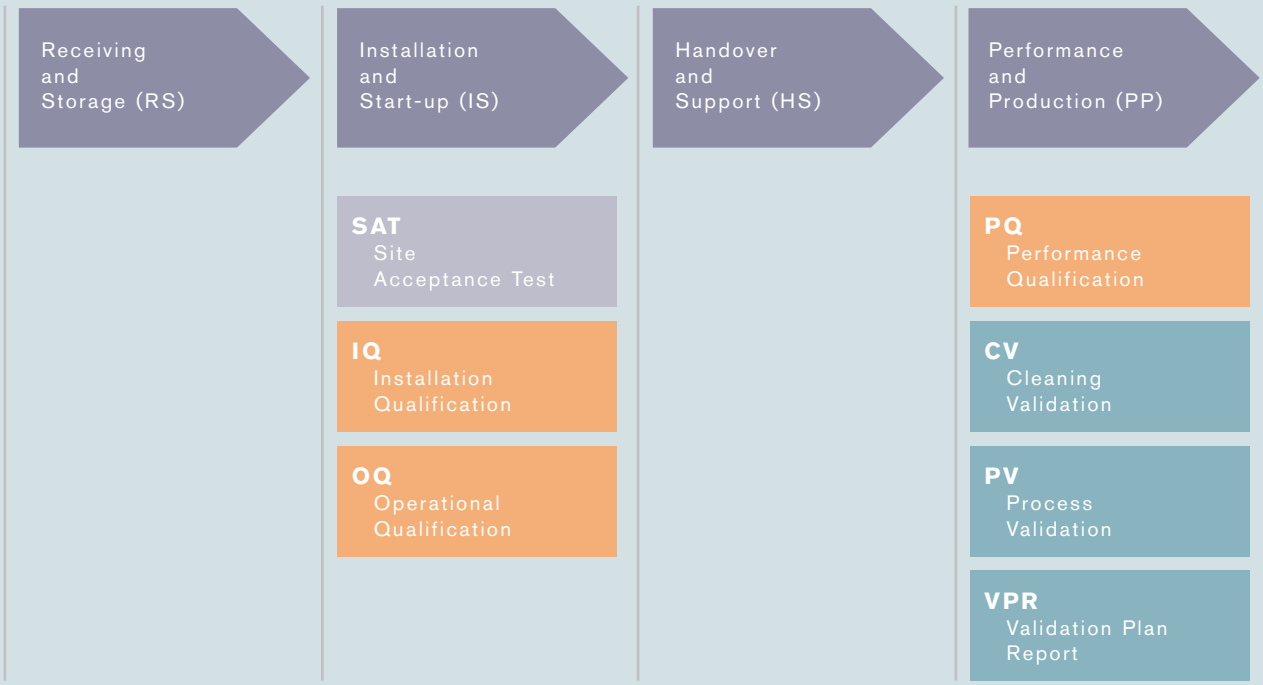
SPX FLOW's state-of-the-art test facility close to Copenhagen in Denmark enables customers to test new products and to evaluate process conditions to secure precise synergy between optimisation of the plant concept and reproducible product quality.

Alternatively, we can install small scale test plants at your site for a limited period for demonstration purposes or pilot-scale production.

LIFELONG SERVICE AND SUPPORT

Our worldwide service organization is ready at all times to provide any necessary spare parts at short notice. We can also send service technicians to help you rectify any problems, thus reducing unscheduled downtime to a minimum.

We offer a number of service agreement options, depending on your individual needs, and our pilot plant engineers are always available to provide applications and development support.



Anhydro Drying Systems for the Pharmaceutical Industry

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