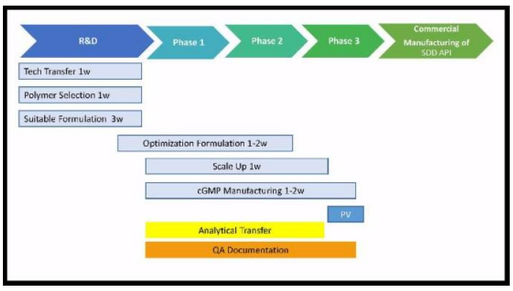
Fuji Chemical Industries USA, Inc.

Fuji Spray Drying Newsletter

Vol 2: Timeline, GMP compliance, and API Synthesis

On-time Delivery

Fuji regards each customer's schedule as a high priority, understanding the primary objective is an early FDA submission , approval , and launch of their new drug. The diagram on the right gives you the timeline for each activity. Fuji has built its team to complete the process development, analytical testing, and manufacturing process to deliver on time , on budget, results.



GMP Compliance

'81	'83	'85	'89	'95	'99	'04	'08	'10	'12	'13	'16
FDA	FDA	FDA	FDA	FDA	FDA	FDA	KFDA	FDA	FDA EMA	FDA	FDA TMMDA

Since 1981, Fuji has successfully passed over 10 inspections by oversea regulatory bodies including the FDA . Fuji has also been passing inspections by local authorities (PMDA and Toyama Prefecture). Our QA team does not only insure our GMP compliance but also offers robust documentation support for our customers.

API Synthesis

Fuji also offers its synthesis facilities for contract manufacturing, giving our customers option to synthesize the API and spray-dry the material at the same site. Here are some highlights:

- Produces 1,000 MT of APIs
- Total Reactor Volume: 100 m^3
- Crystallizers (up to 6,000 L)
- Reactors (up to 9,000 L)
- Extreme temperatures

- Cryogenic reactions: -80°C (1500 L)
- High temp. reactions: +250°C (200 L)

- Hydrogenation to 8 bars (120 psi)
- Handling of corrosives: Br_2, SO_3, Cl_2, Chlorosulfonic acid
- Handling of sulfides and mercaptans
- Able to convert APIs that normally become oily into powder form (Combination with Spray Drying)

In this issue of our technical newsletter, we have shown you an outline of our technical service and GMP support. For more details, please contact our U.S. office below:

Fuji Chemical Industries USA, Inc.

Phone: +1-609-386-3030
US Toll-free: 877-385-4777
Fax: 609-386-3033
Email: contact@fujichemicalusa.com