

## Driving the Pharmaceutical and Biotech Industries towards Excellence in Manufacturing, Supply and Quality

### PROCESS IMPROVEMENT AND PROCESS TECHNOLOGY

NDA consultants have helped clients improve; their manufacturing processes, process understanding, process control and capability. They have identified, developed and industrialized novel state of the art technology solutions for advanced drug delivery and/or drug manufacturing systems.

NDA consultants operate across all the stages of the product development and commercialization life cycle, in support of R&D and Manufacturing and/or Supply organizations. An integrated, end-to-end approach fully aligned with the client's business model, strategies and organization goals; enables compelling business benefits to be achieved.

NDA can provide process and technology solution consultancy over a range of Pharmaceutical and Consumer Healthcare client requirements, including:

- Supporting technology capital investment plans, by defining approaches, options and selecting the optimum process and technology solutions
- Developing technology investment strategies and roadmaps
- Proving new technology concepts, from feasibility and proof of principle studies through to equipment prototyping and industrialization
- Researching and recommending alternative technology approaches, such as continuous manufacturing and process intensification
- Finding novel drug delivery systems for new drugs, product extensions or combination therapy products

NDA consultants have many years of Pharmaceuticals and Consumer Healthcare R&D and Manufacturing experience and have successfully implemented numerous new product and new technology projects. We can help you transform your current drug deliver and manufacturing capabilities, or help you find the optimum solutions for you new molecular entities.

### PROCESS IMPROVEMENT CASE STUDY

#### ISSUE:

A pharmaceutical company needed to radically improve its current Active Pharmaceutical Ingredients (API) manufacturing process to significantly improve operational costs, yield and efficiencies. The company was considering moving from classical batch-based manufacturing to emerging continuous processing technology. However it was not sufficiently familiar with the latest proven technologies that may offer beneficial solutions, to make an informed decision on which way to progress.

#### OBJECTIVE:

Conduct a thorough baseline study, using a combination of interviewing known relevant industry experts and literature search of:

- Proven micro/meso scale technologies employed globally in the successful, commercial manufacturing of chemicals and/or pharmaceuticals
- Chemical and/or pharmaceutical companies actively utilizing such technologies on an industrial commercial scale
- Equipment and technology suppliers of the above systems
- Independent organizations (such as Universities or Government funded bodies) capable of conducting concept evaluation trials

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## DELIVERABLE:

An NDA consultant was engaged to provide a detailed baseline study report covering the above objectives, with recommendations on follow-up action, including short-listing of the top 3 technology options and companies capable of running proof-of-concept study trials.

Following submission of this report of findings and recommendations, the same consultant was engaged by the Pharma Company to assist with the preparation of a Request For Proposal for the selected 3 companies and subsequently set up the proof-of-concept trials with the chosen company.

## PROCESS TECHNOLOGY CASE STUDY

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### ISSUE:

A pharmaceutical company wanted to create a sustainable Oral Solid Dose (OSD) manufacturing process platform for both its R&D and Manufacturing Operations. This process would be used as the first intent process for all New Molecular Entities designated for OSD presentations. The new platform had to revolutionize the company's current OSD development and manufacturing capabilities, in alignments with the latest regulatory driven QbD and PAT approach but also be based on an in depth understanding of the current Manufacturing Unit Operations (MUO's).

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### OBJECTIVE:

- Create extremely well developed, scientific and engineering based understanding of the current Manufacturing unit operations, and capture this knowledge in detailed world-class process design guides, utilizing internal and external experts
- Apply these process design guides in designing and developing the next generation OSD manufacturing platform, in partnership with the chosen suppliers of the process equipment
- Prove the potential capability of the new OSD platform by creating a fully operational prototype of the main system MUO's

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### DELIVERABLE:

- The publication and training of detailed Process Design Guides for key OSD MUO's, which had to be thoroughly reviewed and approved by identified experts, internal and external to company
- The new continuous manufacturing system platform to be designed, built and fully proven to agreed acceptance criteria by detailed prototype trials, including 50 hours of continuous operation

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## Contact Us

To learn more about how Nick Davies & Associates LLC (NDA) can help you, please contact us:

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