

ACG, Innovation for India's Pharmaceutical Powerhouse

FLEXIBLE, SAFE, AND IN CONTROL

India has emerged as a powerhouse of pharmaceutical manufacturing and is now one of the largest providers of generic drugs globally. Enjoying this very important position in the global pharmaceutical market, India's scientists and engineers are shaping the industry and raising standards.



Figure 1: ACG Worldwide, ACG Pharma Technologies, Satara facility.



Even with a constant drive for success, pharmaceutical producers cannot go it alone. The agile flexibility of OEMs specializing in the pharmaceutical industries has harnessed their decades of experience and leveraged “blue sky thinking” to introduce the latest technologies. Collectively, this is their competitive edge: high-end process solutions to advantage India’s pharmaceutical manufacturing.

In this article, I would like to introduce you to one of the pillars of this sector. Since the 1960s, ACG Worldwide has had its finger on the pulse of global pharmaceutical manufacturing. Originally producing hard capsules used in final drug manufacturing, ACG realized there was a huge international potential for its product. It heavily invested in upgrading its plants and processes to become a world-

Having accomplished this, ACG is now being recognized globally for its capsule filling, solid dose and packaging equipment. ACG enlarged its scope of talent quickly; moving further upstream in the manufacturing process in response to industry demands for its expertise of solutions in chemical process technologies. This is how ACG Pharma Technologies was born. It now produces a wide range of fluid-bed solutions for granulation, drying, and pellet coating. This transition into fluid-bed process equipment also required a transition in automation technology. The previous technology was more suited to the requirements of discrete control, but this new process environment needed automation especially designed to meet the needs of process control.

“The zenon software and the batch control software products from COPA-DATA have proven to be the perfect platform for our new configurable X-ONE COMMAND control system. The new X-ONE COMMAND control system from APT fulfills all the requirements of batch control machines in the pharma industry by following the GAMP 5 guidelines, the modular S-88 standards as well as the GMP and the FDA 21 CFR Part 11 requirements in a master product development lifecycle. With X-ONE COMMAND and zenon Batch Control, including its MES or ERP interfaces, our pharma customers receive a high-quality control platform for any new batch control machine equipment. It is also the perfect way to upgrade and qualify any existing batch control machine by following the pharma GMP requirements for control systems.”

KLAUS FEUCHTMANN,

PROJECT LEADER AUTOMATION, XERTECS GMBH, GERMANY

class provider for the global pharmaceutical industry. The phenomenal success that ACG generated and the knowledge gained during this optimization led to a wealth of expertise which would go on to shape a group of world-class companies dedicated to the pharmaceutical industry.

ACG’s expertise generated opportunities to support and optimize its customers’ production facilities. Valuable knowledge which embraced wider process elements beyond capsule manufacturing evolved a few decades ago when ACG began to develop new machines for the innovation-hungry Indian pharmaceutical producers. ACG led the way: producing machines for filling powders, liquids, pastes, and combinations in capsules, plus equipment for the solid dose stages of tableting, inspection, and soft gel manufacture.

ACG was already well acquainted with COPA-DATA, using zenon as standard on some of its machines’ equipment automation. During this collaboration, an understanding developed between ACG and COPA-DATA India – and more specifically with ACG Pharma Technologies – where we were privileged to be involved in the concept discussion for the new process fluid-bed systems for drying, spray granulation and spray coating.

It was natural to evolve in this way, building on ACG’s successfully proven automation technology. zenon provided the desired flexibility, especially with GAMP 5 adherence and FDA 21 CFR Part 11 compliance; a global product on the global stage of international regulations and industry best practice.



Figure 2: In the flesh, ACG Pharma Technologies steel work construction of fluid-bed systems.

To secure global expertise in this new field, ACG partnered with Xertecs GmbH, which operates internationally from its European and US offices. Xertecs specializes in the implementation of technology, processes and services for the pharmaceutical industry. Specifically, for ACG Pharma Technologies, Xertecs's direct experience of excellence in fluid-bed systems, and their adroitness in key international regulations and certifications, provided a powerful partnership – combining the highest levels of innovation with maximum flexibility.

ACG's fluid-bed solutions needed process control at a machine level, in a self-contained system. The initial sketches described the following requirements:

- Process control
- Scalable technology
- Part 11 compliance, audit trail, alarm management, user administration, Historian, reporting
- Integration to higher level system, ERP, MES, SQL

- GAMP 5 guideline best practices, software category 4 (configurable system)
- Process modifications by the end customer, not automation engineers
- Flexible and agile processes
- Reduce risk exposure as far as possible
- Efficient validation

For the team at COPA-DATA, these requirements echoed the initial use cases we developed for zenon's Batch module, the backbone on which the module was designed. The zenon Batch Control module is scalable – from entire plant control with multiple concurrent batches and Historian, through to single use on individual production lines or, as in this case, individual machines. It integrates seamlessly into the zenon environment, where zenon supports Part 11 compliance and GAMP 5 adherence, to create a very flexible end product for ACG.

A solution resulted that combines the process knowledge and control in an environment that allows for new process

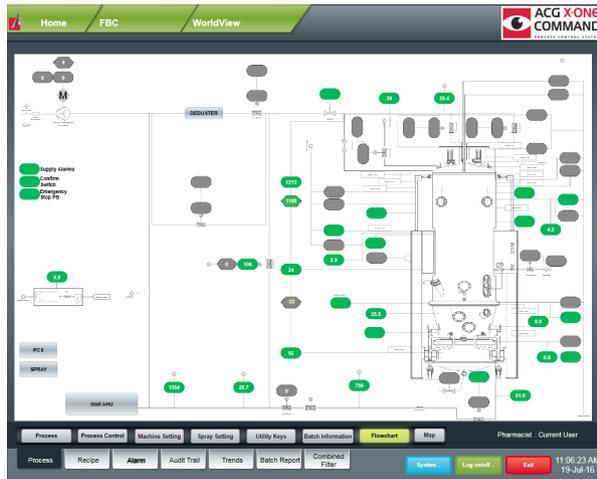


Figure 3: ACG X-ONE COMMAND system: Process overview.



Figure 4: ACG X-ONE COMMAND system: Batch recipe.

recipes to be created without the need for an automation engineer to be involved: a living example of “you innovate and we take care of the compliance”. Adhering to the GAMP 5 guidelines positively impacts the validation necessary to qualify equipment for its intended purpose: reducing effort, time and cost at the end customer’s site. zenon’s connectivity allows for a smooth integration into a facility’s supply chain, MES, ERP and user management system, and is flexible to accommodate the end customers’ QMS.

In pharmaceutical production equipment, the user interface is a critical element. This is the window where the end customer sees the benefits of the machine solution, and where the regulatory data is controlled and generated. The system needs to comply with international regulations (e.g. FDA Part 11), it needs to be robust with very long uptimes, and have a variety of functional roles depending on who uses it. The automation solution needs to integrate

seamlessly into each customer’s unique production and quality system, as this is the junction between the effective equipment technology and the customer’s operational procedures. The connectivity and functionality of zenon create a robust and competent control environment to fulfil the process needs, the flexibility of configuration allows for a smooth interface into the wider production systems, and all this is achieved under the watchful eye of the strict regulations and industry best practices.

The principles of Batch Control defined in the ISA-88 standard has some very desirable features, especially in the regulated industries of pharmaceutical production. Batch Control separates the direct physical control of the equipment in the PLC logic, with its real-world variables and many control elements, from the process control arena, with its process control loops and process parameters.

“The batch control module from COPA-DATA has given us a perfect base on which to provide a value solution to our customers for recipe management. Various permutations and combinations of process parameters at different process stages are simple to achieve with the help of pre-validated modules. In this way, zenon supports flawless configuration in our project development. We greatly appreciate zenon – and the efforts of COPA-DATA and Maestro Technologies, who have supported us in adopting this technology and integrating it in our projects.”

SUDHIR KALKAR, GM TECHNICAL, ACG PHARMA TECHNOLOGIES, INDIA



ABOUT ACG PHARMA TECHNOLOGIES:

ACG Pharma Technologies is a member of ACG Worldwide. With over fifty years of industry experience, ACG Worldwide is an integrated processing, manufacturing and packaging solutions provider for the global pharmaceutical industry. The Group synergistically integrates businesses right from granulation and tablet coating equipment to hard capsules and capsule-filling machines; barrier packaging films to blister packing and cartoning machines; tablet compression systems to tablet tooling; vision inspection systems to end-of-line packaging solutions. With the backing of a dedicated R&D facility - SciTech Center - in Mumbai, India, ACG has been committed towards continuous investment in innovative products and technologies that serve the pharmaceutical industry. Recognized as 'Best Vendor' by OPPI, ACG has also bagged awards for several innovative products from IIP & Pharmexcil. ACG serves customers in more than 100 countries and has its subsidiaries in Brazil, China, Indonesia, the US and the UK. Find out more at www.acg-world.com or www.acg-pharmatechnologies.com.

Learn, how you too, can enhance your batch production with zenon Batch Control. Fact Sheet, videos and more at your fingertips!

<http://kaywa.me/UsZ7T>



Effectively, the zenon Batch Control module lifts the process control out of the intricate world of automation engineering. It allows process engineers the vision to see the fluid and chemical chains, and have a tool at their fingertips to put this into action. They don't need to know anything about automation or individual variables. They simply drag and drop pre-validated phases to define the process, then zenon effectively executes the process control. A process environment, for process engineers: design the automation once and reuse it for many different products.

ACG's vision is to be globally recognized for pioneering new technology and nurturing talent to attain successful products and services in a demanding complex industry. It is a pleasure to have zenon operating within this sphere of expert knowledge, and to be a part of making the "blue sky thinking" a reality at ACG.

ROBERT HARRISON,
INDUSTRY MANAGER PHARMACEUTICAL