

Case study

Organichem Corporation

Rensselaer, New York



Pharmaceutical plant expansion exemplifies industry shift to contract manufacturing

Organichem Corporation offers a wide range of third-party development and manufacturing capabilities to chemical and pharmaceutical companies. It is a world leader in contract manufacturing of bulk active pharmaceutical ingredients. Products manufactured by Organichem include controlled substances, cancer-fighting drugs, and diagnostic imaging agents.

Organichem's 23-acre complex near Albany provides a window into the future of the pharmaceutical industry. Most major drug companies no longer handle everything internally. They are increasingly outsourcing research, development, and manufacturing. Large and small pharmaceutical firms rely on companies like Organichem to produce pilot batches of new drugs for testing purposes. If the tests are successful, these third-party firms then manufacture the drugs commercially.

To meet growing demand, Organichem began expanding its production capacity in June 2002 with the construction of a new 20,000-square-foot manufacturing building with four potent compound production suites. Plans are in place and construction has started to expand the building to include twelve more production suites.

The company is teaming with Johnson Controls to provide precise control of temperature, humidity, ventilation, pressurization, and security in the new building – all of which are essential to achieving FDA validation. An equally important component of FDA approval is the documentation provided by these control systems. The documentation ensures that proper environmental conditions are being met consistently through all phases of product development and manufacturing.



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J.P. MONTEAU
DIRECTOR OF ENGINEERING,
ENVIRONMENTAL SAFETY, AND HEALTH
ORGANICHEM CORPORATION

"Our industry is highly regulated, and it's becoming more regulated," said J.P. Monteau, Organichem's Director of Engineering, Environmental Safety, and Health. "Our clients are asking us to go beyond what's required by the FDA. That's what we did in this new building. We had to showcase the facility so that we could sell it to our clients."

Fast-track installation and validation

Organichem's new production suite had to be built quickly in order to meet the startup date for production of a new oncologic, or anti-cancer, drug. Johnson Controls had only three months to design, install, and commission its Metasys® building automation system – at the same time that mechanical systems were being constructed. There was no margin for error in the control system installation because it plays such an integral role in eventual FDA validation.

"Quite often, our customers do not have any manufacturing facilities," said Monteau. "That's why they come to us. If we don't follow the FDA guidelines to a tee, they can come in and cite us. That means the drug may not be approved."

The Johnson Controls Metasys system provides FDA validation documentation in three essential areas:

- Installation Qualification
- Operational Qualification
- Performance Qualification

Pressurization protects sensitive drug

An air pressurization scheme was necessary to protect the sensitive oncologic drug from the environment outside the production room. And since it is highly potent, there had to

be assurances that, in case a problem occurred, nothing would escape the lab and spread through the building.

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Security system employs hand geometry

Johnson Controls also installed a sophisticated security system concurrent with the plant expansion project. The Cardkey® P2000 security system allows Organichem to limit access to certain parts of the complex until people have met specified training or medical surveillance requirements.

Along with the traditional proximity card readers for access, the system also makes use of biometrics. If a person's hand geometry pattern does not match a list of authorized patterns for a specific space, the P2000 system will not allow the person access to that space.

"If we're dealing with a narcotic, very few people will be authorized to work on its production," said Monteau. "If you're going into an area where we're making oncologic products, you may need to be medically cleared – either by attaining certain medical training or passing a physical exam."

The P2000 also replaces Organichem's existing security system, which performed traditional building access functions.

"We didn't want to have two separate systems – one for regular card access and one for limited access," said Monteau.

"The great thing about Johnson Controls is now we have it all in one system."