



FLEXPRO 50

POTENT PROCESSING - FLEXIBILITY - PARTNERSHIP



groninger & co. gmbh
Hofäckerstraße 9
74564 Crailsheim
Germany
Phone +49 7951 495-0
Fax +49 7951 495-3138
office@groninger.de

www.groninger.de

groninger GmbH & Co. KG
Birkenbergstraße 1
91625 Schnelldorf
Germany
Phone +49 7950 800-0
Fax +49 7950 800-2123
office@groninger.de

www.groninger.de



Franz Ziel GmbH
Raiffeisenstr. 33
48727 Billerbeck
Germany
Phone +49 2543 2335-0
Fax +49 2543 2335-29
mail@ziel-gmbh.com

www.ziel-gmbh.com

Franz Ziel USA Inc.
3049 Southcross Boulevard
Suite 100
Rock Hill, South Carolina 29730
Phone +1 803 324 9435
Fax +1 803 324 9436
mail@ziel-usa.com

www.ziel-usa.com



Martin Christ Gefriertrocknungsanlagen GmbH
An der Unteren Söse 50
37520 Osterode am Harz
Germany
Phone +49 5522 5007-0
Fax +49 5522 5007-12
info@martinchrist.de

www.martinchrist.de

Awarded 2018 with the
**INTERPHEX Biotech
Innovation Award**



A strong partnership

3 partners who offer you concentrated expertise



We fill Visions with Life

Filling, closing and handling machines for the pharmaceutical, consumer healthcare and cosmetics industries

groninger is one of the world's leading manufacturers of filling and sealing machines for the pharmaceutical, cosmetics and consumer healthcare industries. The slogan "We fill Visions with Life" aptly describes what groninger stands for: excellent know-how, innovative solutions and partnership-based cooperation in the specialized engineering sector. Since it was founded by Horst Groninger in 1980 the company has become a hidden champion and innovation leader in the industry. Today the company, managed by the family's second generation, employs around 1,300 people at its sites in Crailsheim, Schnelldorf and Charlotte (USA). The company is headquartered in Crailsheim.

Location Crailsheim, Schnelldorf (Germany), Charlotte (USA)
Founded 1980
Employees 1,300

www.groninger.de



Protecting Life with Technology

Customized isolators for personal and product protection as containment for aseptic or toxic processes

Nearly four decades of cleanroom experience and expertise under our belt have made us a leading company in this field. One of our core competences is the complex process of Aseptic Processing in the Pharmaceutical Industry. We are able to provide you a customized, GMP-compliant, high-quality (made in Germany) turnkey solution for your aseptic processing demands. FZ designs and builds customized isolators for personal and product protection as containment for aseptic or toxic processes. Apart from that we are a full provider of all needed hardware and services around it to minimize interface adaptations and ensure data integrity. These complete solutions make it much easier for you to plan and start your production line while ensuring optimized workflow and GMP-compliance.

Location Billerbeck (Germany), Rock Hill (USA)
Founded 1982
Employees 170

www.ziel-gmbh.com



We Create Values

Freeze dryers and automatic loading and unloading systems for the highest demands of the pharmaceutical industry

Martin Christ Gefriertrocknungsanlagen GmbH is a world leading company in the development and manufacture of freeze drying systems. With our long term experience and an export share of more than 70% we are globally active. The name Martin Christ stands for utmost satisfaction of our customers. We develop and manufacture for the highest demands of the pharmaceutical industry. We see ourselves as a worldwide leader in innovation, and we regard our commitment to research and development as a major duty. Even more importantly, it is our greatest passion. We constantly secure our position as an international leader by means of technological innovations.

Location Osterode (Germany)
Founded 1947
Employees 150

www.martinchrist.de

Meeting the requirements & challenges

of manufacturing today and in the future



These new drugs are produced in smaller batch sizes compared to previous commercial products with much higher process requirements:

- Meeting all aseptic and containment requirements per regulatory agencies
- Different zone concepts to process drugs with various OEB and BSL levels
- Ergonomically designed with operator and interventions considered
- Capable of processing multiple formats with minimal changeover parts
- Designed for zero product loss
- Optimal line accessibility for ease of handling and cleaning to avoid cross contamination

These market requirements are driving us every day to become even better. Experience the modular and standardized FlexPro50 machine portfolio to bring your product faster to the market.

Our solution: New Flexibility with Proven Technology

FlexPro 50: Modular machine concept for aseptic and aseptic toxic processing of syringes, cartridges, vials and eye drop container



Technical features

Designed for highest OEB and BSL level

Processing of up to 5,000 objects/h

RTU container up to 4" tub-size

Vials in bulk, trays and eye drop containers

Manual or fully automated IPC up to 100%

Peristaltic pumps, rotary piston pumps or combi filling system

Designed to use Groninger single-use rotary piston pumps

Nitrogen gassing during filling and stoppering

Vacuum filling and stoppering

Robotic denesting and single-reject

CE and UL version

Changeover time including VHP cycle of around 2 hrs

Siemens and Rockwell controls

21 CFR Part 11 compliance



FlexPro50 installations worldwide

Our Highlights



Total isolator height of 3 meter / 10ft:

The integrated Franz Ziel isolator technology fits in a standard clean room. Ideal for retrofits in existing facilities or modular facilities where no technical area is limited or even not available.



Robotic handling:

Eliminates human intervention and reduces risk to products.



3 formats on 1 platform:

Processing of syringes, cartridges and vials.



Containment

The integrated automatic (via HMI) Toxic Air Filter Module (FZ-ATAF) is installed close to the contamination source and reliably prevents leakage of highly active substances. Convenient operation by HMI, easy cleaning (WiP) and safe (OEB6).



LyoShuttle Loading System

Integration of Martin Christ's LyoShuttle - the innovative, robust, and wireless isolator-friendly loading and unloading system freeze dryer.



Operator friendly

Ergonomically designed with operator and interventions considered to reduce risk.

...and many more

Fully automated processes:

The fully automated line execution eliminates the need for human intervention into the filling line.

Freeze drying capabilities:

The Martin Christ portfolio offers state of the art freeze dryers with a wide range of PAT-Tools and SCADA-System LPCplus.

Infeed transfer options:

The groninger No-Touch-Transfer and the Franz Ziel H₂O₂ chamber provide safe and simple transfers of RTU containers into the isolator.

Zone concepts:

With individually controlled isolator modules, different requirements for various OEB and BSL levels can be met.

Smart fill technology:

groninger offers a wide range of features to eliminate product waste during priming, production and run-empty phases.

Complete Downstream Equipment:

groninger offers a comprehensive downstream equipment for object processing, from plunger rod insertion to safety device assembly and labelling.

Quick Connect philosophy:

Designed for tool-less change over and minimal format parts.

Flexibility:

Capable of processing nested syringes, cartridges and vials in one line configuration and bulk vials, trayed vials and eye drop container by exchanging machine trolleys.

Additional equipment features

Our Accessories for FlexPro50



Rapid Decontamination System (FZ-RDS)

The FZ RDS enables the off-line sterilization by an integrated vH_2O_2 gas supply system of monitoring material and small tools for a smooth process operation.

PAT Tools
Innovative Martin Christ freeze drying tools like the wireless temperature sensors WTMplus or the camera system LyoCam support monitoring of the freeze drying cycle from start to end.



Infeed Options

The No-Touch-Transfer Technology or a H_2O_2 outside decontamination system can be used to transfer RTU containers directly into the isolator.



Wash-In-Place (WIP) Kit

To avoid cross contamination on multi product lines the FlexPro offers manual and fully automated cleaning processes.

Project Management

A joint project plan and one contact person for the customer can be offered for turnkey projects.

Glove Testing System

The FZ-GTS Wi-Fi Glove Testing System with the latest Glove Test 4.0 software enables concurrently cable-free / tubeless leak testing of multiple gloves installed in an isolator.



GMP compliance

The FlexPro team support with any GMP related questions.

Single-Use-Filling Technology

Experience the greatest flexibility with the groninger single tube peristaltic pumps or the unique single-use rotary piston pumps.



External washing equipment

The groninger outside washing machine is the ideal equipment when processing potent drugs.

Qualification

The FlexPro team supports with qualification support of the line, especially around the NTT processes.

Risk analysis

A risk analysis can be executed to determine e.g. the relevant monitoring locations.

With new requirements and changes in the industry, pharma customers demand today a much higher process know-how and expertise from their vendors of fill&finish equipment. Especially Biotec companies rely on proven equipment, features and process know-how of their partners to mitigate risks and to shorten their time-to-market.

The FlexPro 50 partners have identified these needs and have developed a comprehensive and proven portfolio of accessories around the filling equipment to help customers far and beyond just the filling line.



A success story –

EirGen Pharma, a CMO specialized in potent processing



” With the FlexPro50, we accommodate all our requirements as a CMO for potent products. “

Dermot O’Riordan, Sterile Technical Operations Manager



About EirGen

EirGen Pharma is a world leading developer and commercial supplier of specialty medicines to the global market

Sector	Pharmaceuticals
Special field	High Potency Pharmaceutical Products, Oncology & Cytotoxic products, EMA, FDA & PMDA approved facility, High Containment product development & manufacture, Sterile Fill Finish, Microbiology, Global Supply Chain und Research & Development
Location	Waterford (Ireland)
Founding	2005

EirGen Pharma is a world leading developer and commercial supplier of specialty medicines to the global market and has a reputation for excellence and quality in the fast moving, competitive pharmaceutical industry. We provide versatile, price effective and efficient solutions to partners seeking to collaborate in pharma healthcare. EirGen has a blemish-free inspection record and is a trusted supplier of best quality, safe and reliable life saving high containment medicines.

With our industry partners and collaborators, we continue to develop an exciting portfolio of high potency pharma products for both human and veterinary use that include:

- New Chemical Entities
- Generic developments
- Advanced formulation development
- Fill Finish of both small molecule and biologics

With the Groninger FlexPro50 line, we are able to accommodate all our requirements as a Contract Manufacturer (CMO) to be able to meet our customer’s expectations.

The process of all RTU container in one line with an minimal amount of changeover time, product saving processes like the Groninger SMART FILL and shortest isolator cycle times allow us to offer our customers the flexibility they need. Additionally, the elimination of any space in a technical floor due to integrated air

handling and controls inside the 3 meter line equipment helped us to reduce our CAPEX significantly for the entire projects and therefore gained great benefits to EIRGEN.

The in-depth knowledge and technical capabilities of our R&D team are fundamental to the development of innovative high containment medicines. At EirGen, our R&D scientists create new products. Both our in-house state of the art R&D laboratories and our commercial operations are situated together in Ireland, Europe.

A success story –

emergent, a CMO specialized in aseptic processing



About emergent

Emergent develops, manufactures, and delivers a portfolio of medical countermeasures for biological and chemical threats, existing and emerging infectious diseases as well as opioid overdose.

Sector	Pharmaceuticals
Special field	Biological Threats, Chemical Threats, Infectious Diseases, Opioid Overdose
Location	Gaithersburg, Maryland
Founding	1998



BJ Hull, Vice President and General Manager

Emergent BioSolutions is a global life sciences company seeking to protect and enhance life by providing specialty products for civilian and military populations that address accidental, deliberate, and naturally occurring public health threats. Emergent manufactures products for our customers that support all phases of clinical trials up to commercial-scale manufacturing. With eight manufacturing facilities globally, Emergent has supported the development of more than 200 clinical candidates for our clients over the years. Emergent's facilities have been audited by multiple regulatory agencies including those in the US, Canada, EU and Japan.

The capabilities reach from processing liquid and lyophilized products, bulk and ready-to-use container to commercial packaging like labeling, inspection and distribution.

"With more than 50 million patients globally, we have a huge responsibility to our clients. To deliver outstanding performance every day, it is mandatory to have reliable partners and state-of-the-art equipment at our facilities. For our latest investment we decided to go with the FlexPro50 machine from Groninger, because it will offer us the flexibility we need to serve our customers.

Proven history of audited lines in the US and overseas, multiple different formats with shortest changeover times and a sophisticated line setup that are ideal for our operators with robotic technology made the difference," says BJ Hull, Vice President and General Manager, Baltimore and Rockville Sites

Future outlook: "Emergent values our partnership with Groninger. The ability to deliver for our customers is key to our long-term success and we are pleased to have the right partners to help with our future expansion plans," said Hull.