

AZENTA
LIFE SCIENCES



**PARTNERS
IN SUCCESS**

Azenta Distributor Meeting – Introduction to Barkey

March 07, 2023

Agenda



Barkey	01
Business Lines	02
Product Portfolio	03
Q&A	04

BARKEY

01

Let's play a game
Poll: Mentimeter



Start Mentimeter

History of continuous innovation



Barkey was founded in 1980 by Volker Barkey. Since then, the basis for today's portfolio grew consistently:



S-LINE
Blood and infusion warmer for transfusion of blood products and infusion solutions



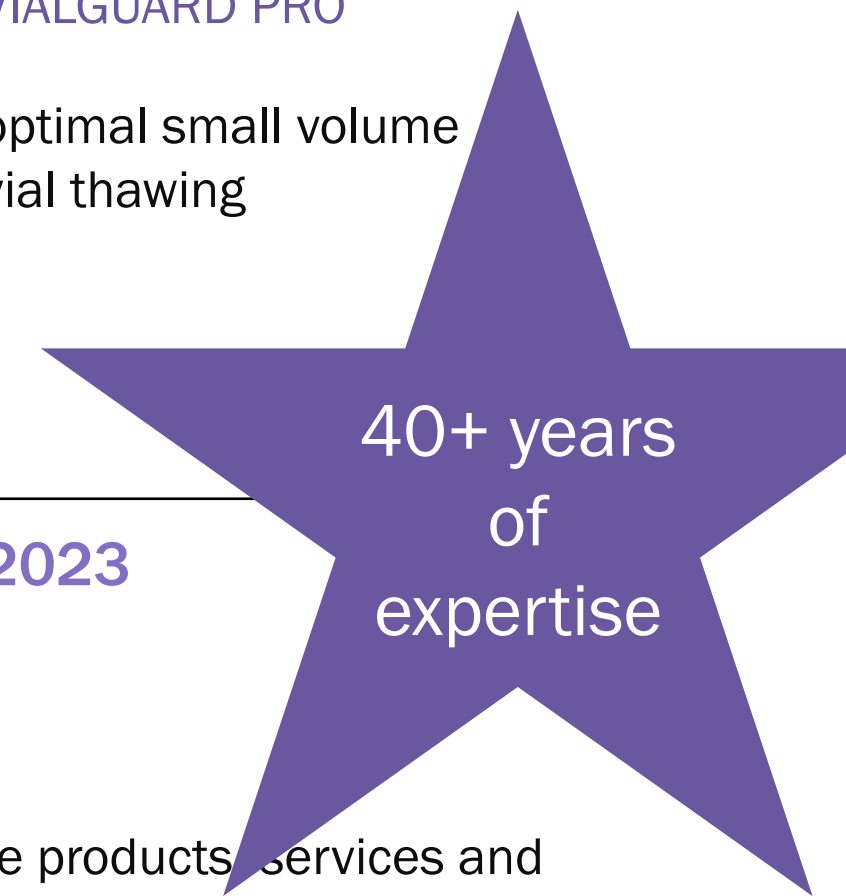
PLASMATHERM V
"The fastest plasmatherm ever" – up to 30% faster than standard one



PLASMATHERM C&G
plasmatherm dedicated for the needs of the CGT



VIALGUARD PRO
optimal small volume vial thawing



1980



CLINITHERM BABY



PLASMATHERM



WARMING CENTER



CLINITHERM PASTEUR



PLASMATHERM DTM

2010



PLASMATHERM DTM V 201
Redesign plasma thawer



WARMING CENTER II
Redesign warming center

2020



VARITHERM
Lab device for temperature control of cell material up to +60°C

Divestment of the neonatology business line

2023

More products, services and accessories to be launched soon

- Warming center C&G for pre-warming of cell media
- Additional platform for thawing vials

Barkey: industry standard for thawing and precision warming

50,000+
units installed

- **Precision warming technologies for biologics, reliability, reproducibility and replicability** with a holistic approach
- **Best-in-class technology** for Cell and Gene Therapy (CGT) is being rapidly adopted by leading **therapeutic developers, CDMOs, hospitals, clinics** for manufacturing and patient administration applications
- Only thawing solutions provider that meets stringent **industry requirements**
- **Part of Azenta Inc. since 1st July 2022**



60+
countries

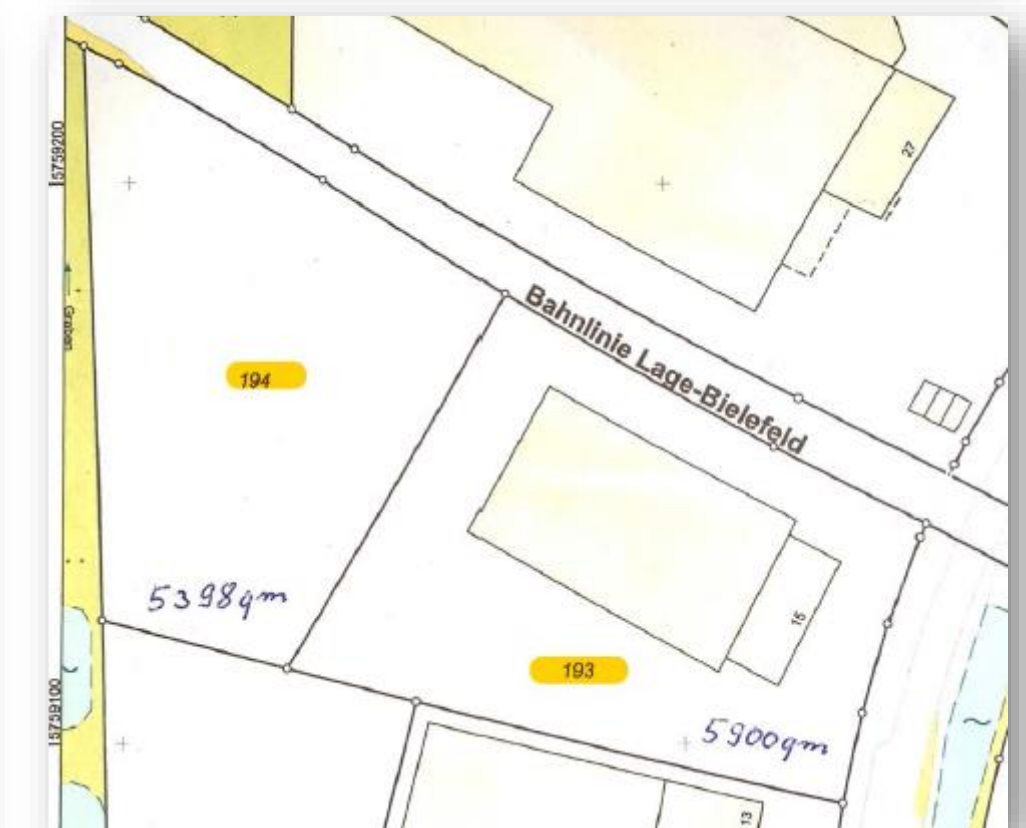
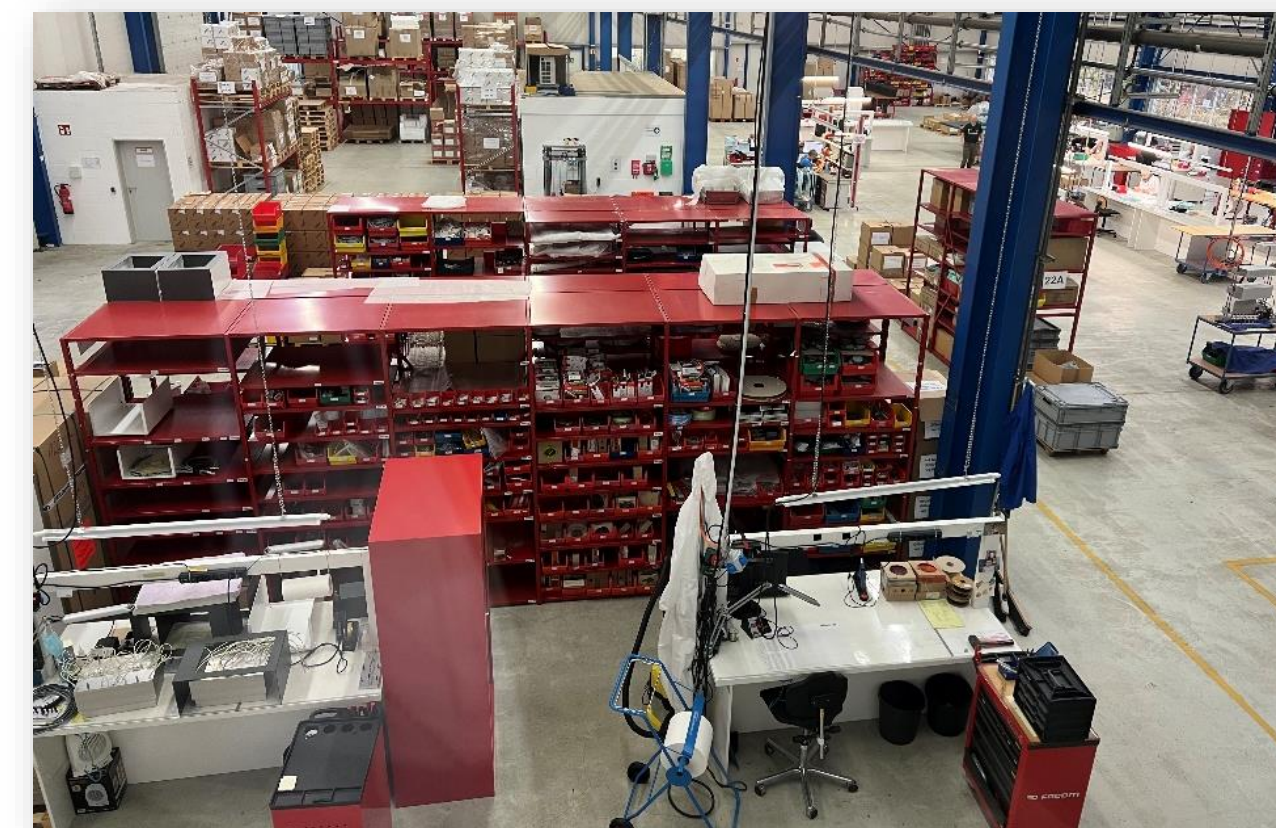
40+
years of innovation
and track record

80+
talented employees

State-of-the-art facility at Barkey's headquarters

Production area: 2,240 sqm
Office space: 1,520 spm
Available land for expansion: 11,500 sqm

- The headquarter is equipped with the state-of-the-art equipment and adheres to FDA approved production processes to meet the quality standards of the most demanding customers
- The two properties (plant I and plant II) have further land available for expansion, which would allow the Company to grow its production facility to minimum 11,000 sqm





BARKEY BUSINESS LINES

Q2

Barkey is the critical part in connecting CGT developers and hospitals



CELL & GENE

- Therapy development
- Clinical trials
- Manufacturing
- Patient administration



- Fastest growing market
- Best fit of product portfolio
- Main driver for innovation
- Direct SALES the key

HOSPITALS

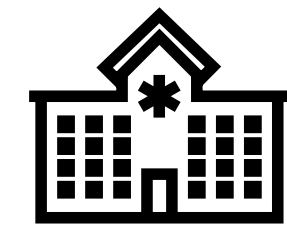
- Hospitals
- Oncology Centers
- Stem Cell Lab



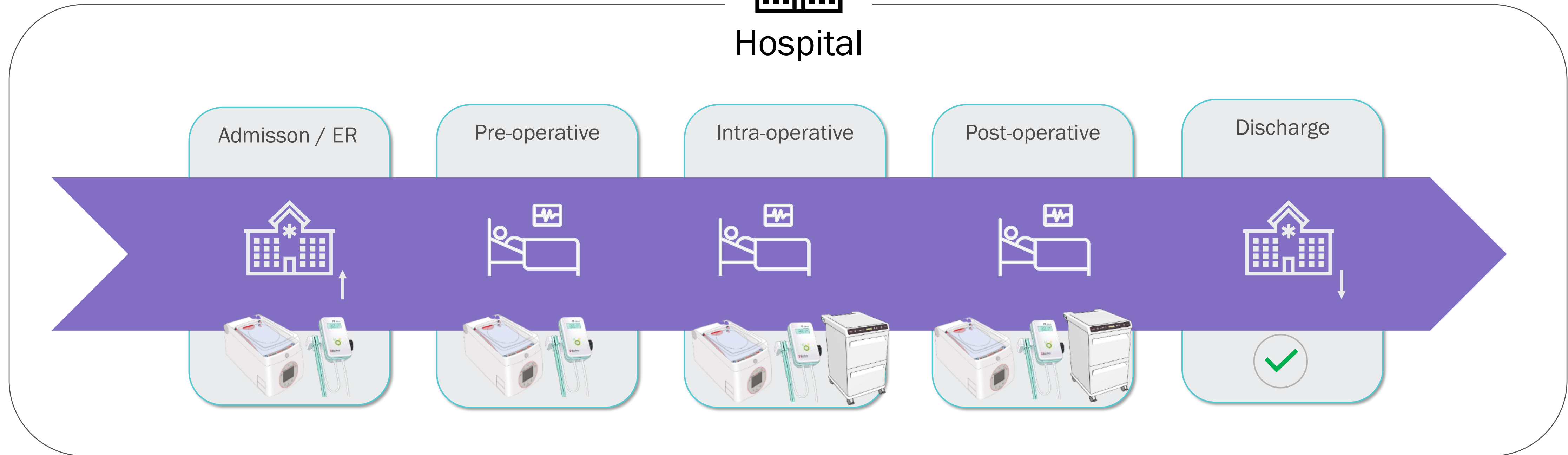
- Constant long-term business
- Premium product portfolio
- Indirect SALES the key

Barkey is the strategically required link between Cell & Gene manufacturers and hospitals.

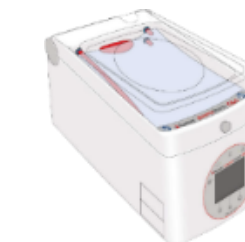
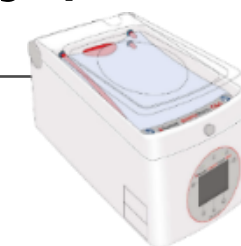
CARE CLINICAL PATHWAY



Hospital



Laboratory / Blood Bank



plasmatherm



S-line

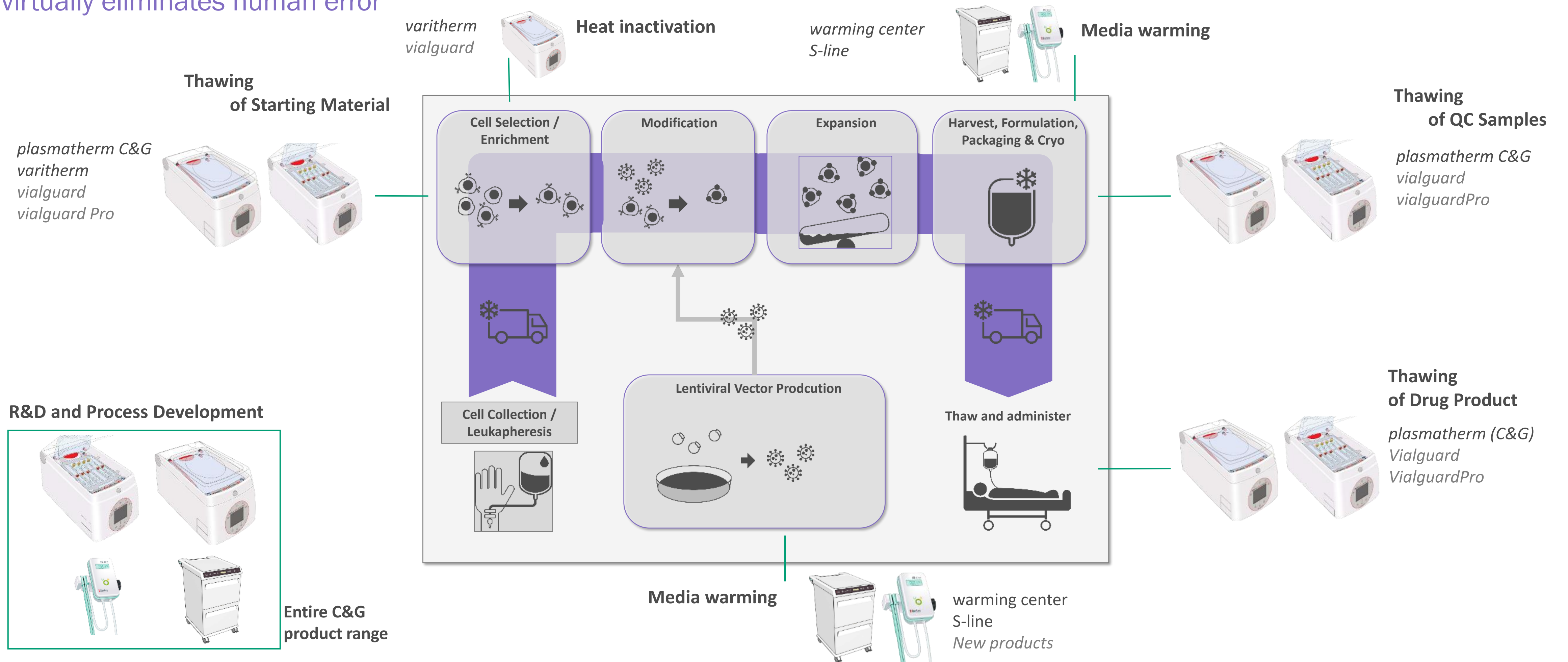


warming center

Barkey's holistic view on the CGT Workflow

From manufacturing to patient administration

The only standardized and universal thawing solution in the market that offers reproducibility and virtually eliminates human error



PRODUCT PORTFOLIO

03

Barkey plasmatherm

The international gold-standard of Plasma (FFP-) Thawing



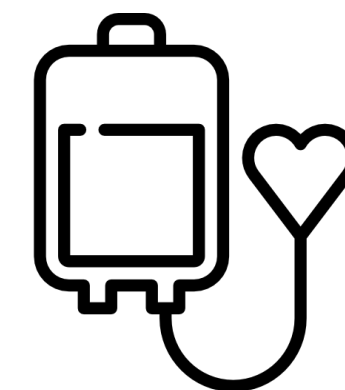
Electronic documentation

Highlights

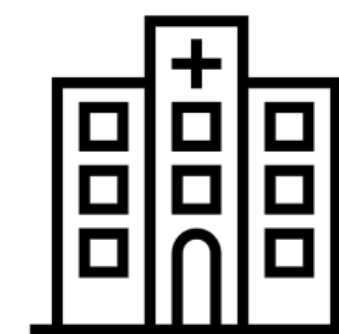
- Plasma dry-thawing and warming device
- FDA/EU approved standard of care at hospitals and clinics administering blood and plasma therapies
- No risk of sample contamination
- Highly hygienic warming solution
- Electronic data documentation with multiple interfaces
- Optimal transition from cryo to 37 °C
- Highly flexible for all types of bags and vials

Adressable markets

Blood Banks



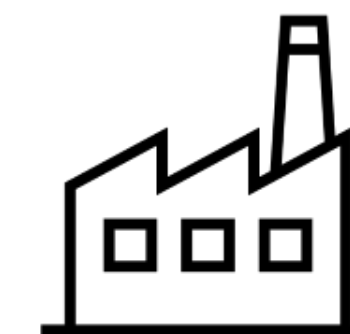
Hospitals



CGT Development



Manufacturing



CDMO



Barkey plasmatherm V

The fastest plasmatherm ever



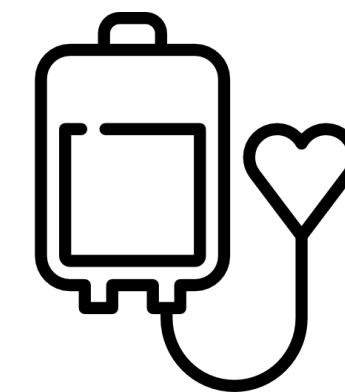
Electronic documentation

Highlights

- Same as Barkey plasmatherm but **up to 30% faster** due to innovative paddle design

Adressable markets

Blood Banks



Hospitals



Critical Care



Dialysis



Barkey plasmatherm C&G

The state-of-the-art cell treatment system



Highlights

- Highly innovative cell treatment system specifically designed for biotechnology applications **up to 37 °C**
- **Replicates the manual swirling process** of water baths with consistency and replicability
- **Even, consistent, temperature and time-controlled** thawing to maintain serums' growth-supporting characteristics
- Highly hygienic warming solution with no risk of sample contamination
- Electronic data documentation with multiple interfaces
- Highly flexible for all types of bags and vials; for laboratory and process development use only

Adressable markets

Laboratories



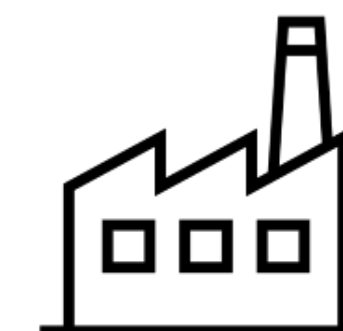
Hospitals



CGT
Development



Manufacturing



CDMO



Barkey varitherm

The state-of-the-art cell treatment system



Highlights

- Highly innovative cell treatment system specifically designed for biotechnology applications **up to 60°C**
- Replicates the manual swirling process of water baths with consistency and replicability
- Even, consistent, temperature and time-controlled thawing to maintain serums' growth-supporting characteristics
- Highly hygienic warming solution with no risk of sample contamination
- Electronic data documentation with multiple interfaces
- Highly flexible for all types of bags and vials; for laboratory and process development use only

Adressable markets

Laboratories



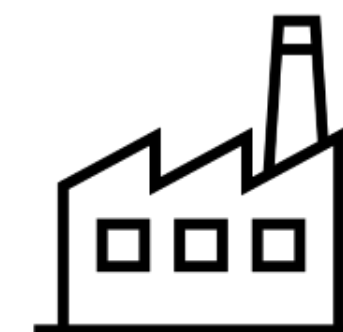
Hospitals



CGT Development



Manufacturing



CDMO



Barkey vialguard pro vertical vial thawing



New product



Electronic documentation

Highlights

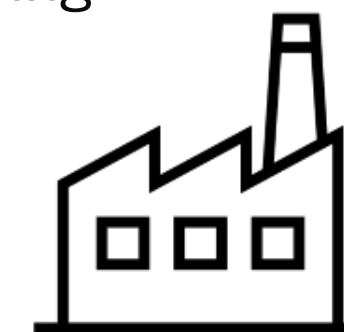
- Vertical vial thawing for small volume vials

Adressable markets

Laboratories



Manufacturing



CDMO



Patient Administration



Barkey S-line

Safe and reliable blood and fluid warming directly to the patient



Highlights

- Fluid warmer transports blood and blood products as well as infusion solutions directly to the patient
- For use in Cell and Gene Therapies and hospitals
- No loss of temperature during transport to the patient
- Highly hygienic warming solution
- Highly flexible for various types of IV-sets
- FDA 510(k) clearance

Addressable markets

Patient Application
Gene Therapy
Infusion



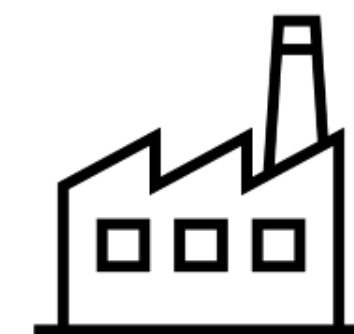
Media
Warming



CGT Development



Manufacturing



CDMO



Barkey autocontrol + autoline

The new standard of infusion



Highlights

- Directs and controls the relevant warming procedure reliably and efficiently
- Only system on the market that ensures a stable temperature from the instrument to the patient due to the integrated tube system
- Ensures safety and temperature control of warm infusion solutions, FFP and blood until the infusion into patients
- Designed for any standard IV set
- Can be applied to the return line of dialysis fluids

Adressable markets

Critical Care



Dialysis



Hospitals



Barkey warming center II + III

Warming cabinets for pre-heating and heating of infusion solutions and textiles

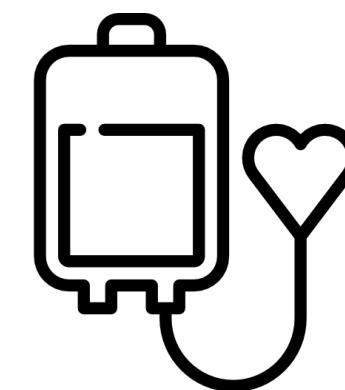


Highlights

- Warms large volumes of infusion bottles, textiles and cell culture media
- Electronic and mechanical overtemperature alarms
- Filter element for avoidance of contaminations of circular air technology and personnel
- High volume capacity (up to 40 liters and 270 liters respectively)
- Manufacturer-calibrated temperature setting at +42 °C and adjustable temperature range from +35 °C to +55 °C

Adressable markets

Blood Banks



Media Warming



Hospitals



Regulations

- Barkey's QM system is based on the **DIN EN ISO 13485**, the Quality System Regulation (QSR) CFR 21 Part 820 of the **US Food and Drug Administration (FDA)** and the national requirements of the individual countries to which devices are exported
- One of the first companies successfully audited according to MDR standard



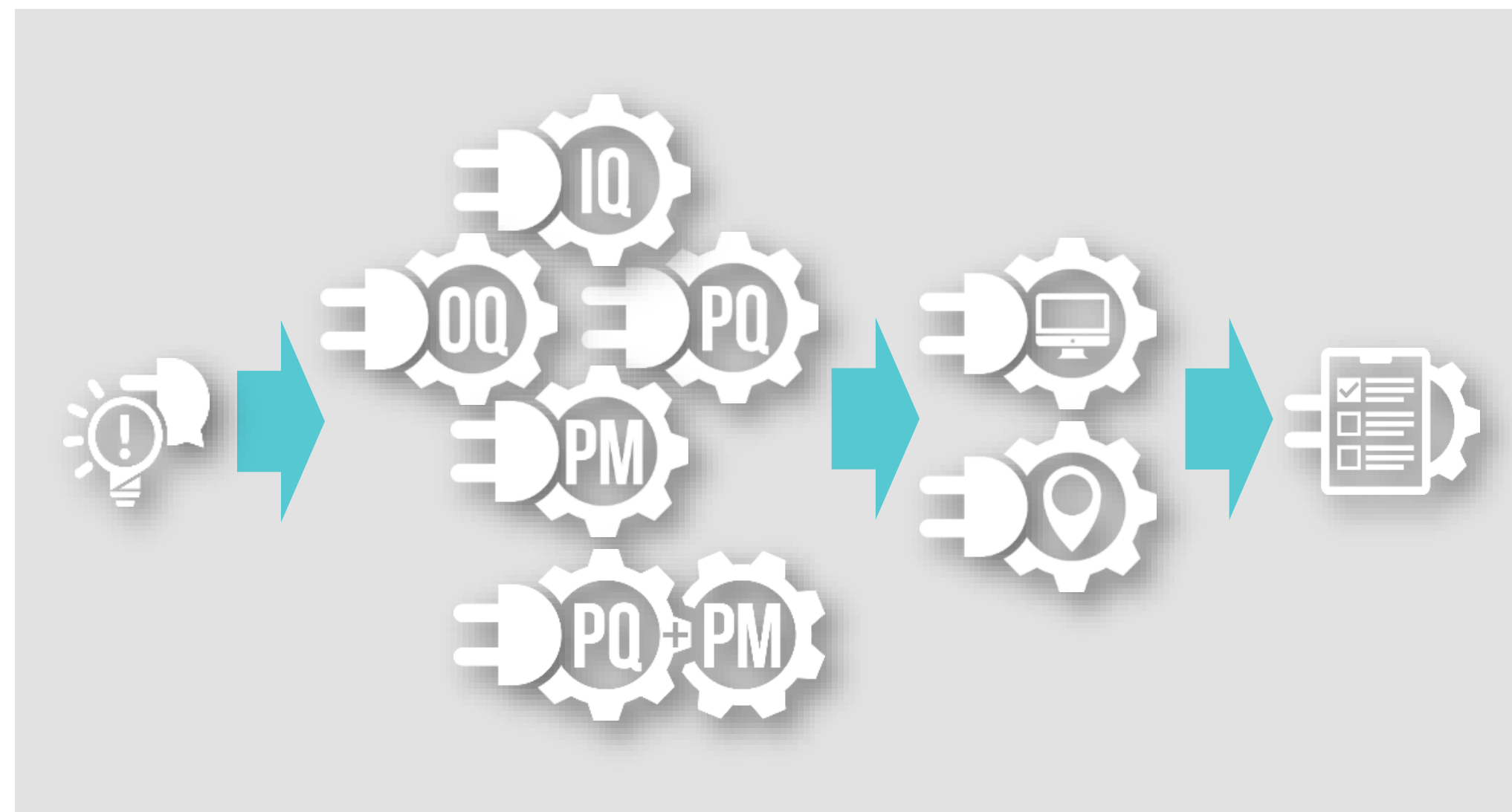
EU Quality Management System Certificate (MDR)

FDA 510(k)

DIN EN ISO 13485

Service IQ OQ PQ

Reliable and thorough services



Highlights

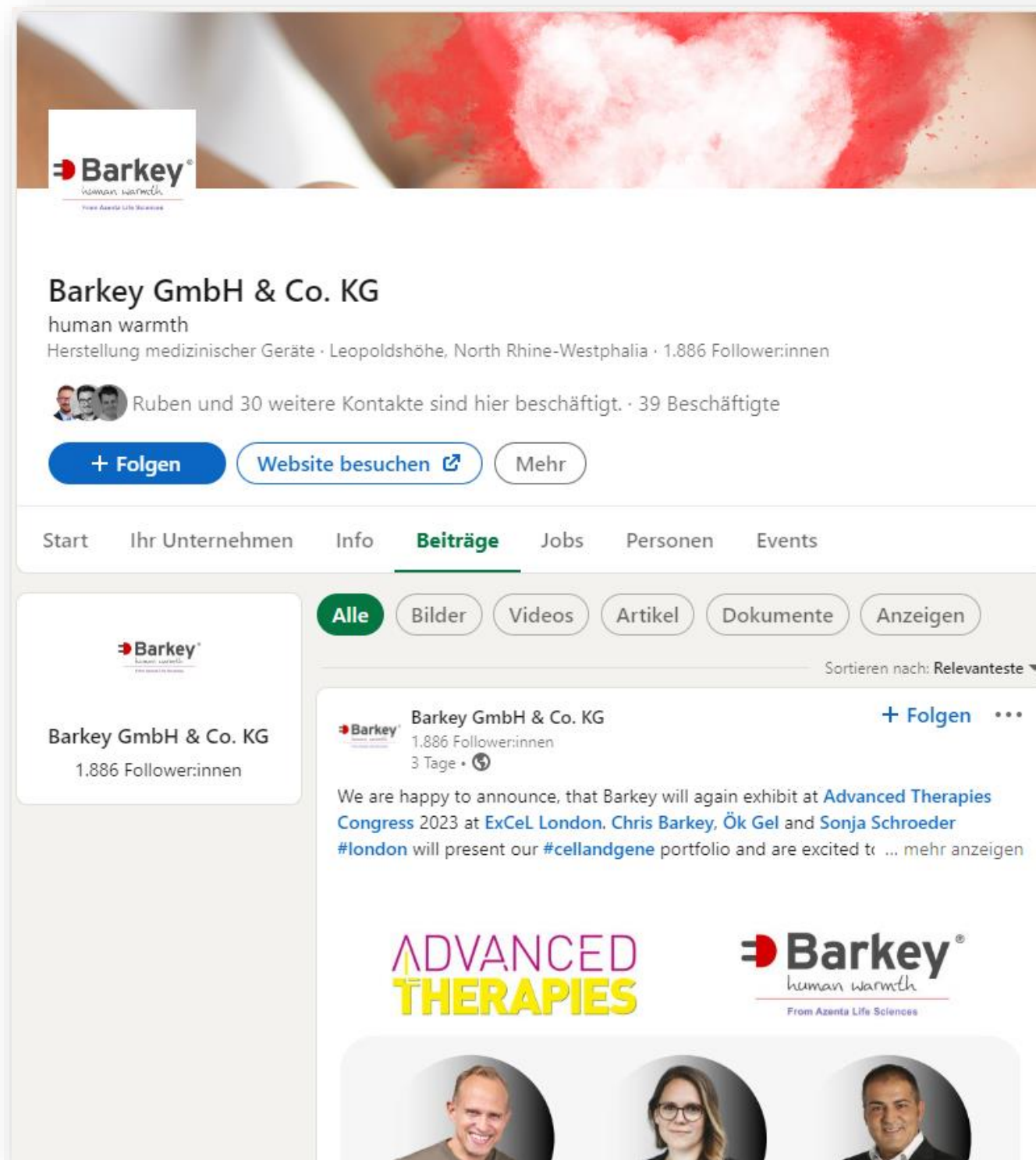
- Services for Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)
- Mandatory to meet cGMP requirements
- For most organizations, equipment qualification and validation is not a constant need, so performing it in-house is seldom feasible
- Repeating business due to re-qualification needs following any major maintenance or equipment modification
- Barkey offers qualified personnel and services to meet the stringent requirements
- Frees up time and attention for customers

Benefits

- Essential annual repeating engagement with customers
- Reinforce intimate relationship with customers

Marketing

Social Media



Events



Product launches



Emily Whitehead foundation

Patient zero came to visit

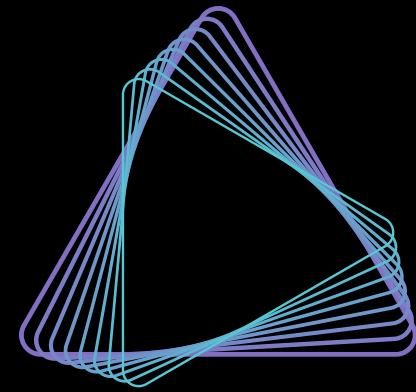


[Video Emily Whitehead Visit](#)



Q&A

04



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Thank you!

