


Krakatoa® K500

The Future of Media and Buffer Manufacturing


Enabling co-location of cell culture media and buffer manufacturing and bioproduction.


Manufacture cell culture media and buffers on-demand at bioreactor scale.

 Pod-based manufacturing system

 Manufactures GMP-grade media solutions at the point of use*

 Produces 35–500 liters per pod

 < 3 hour process time

 Generates automated digital batch records



Transform Your Media and Buffers for Bioproduction

For decades, media and buffers have been a hidden constraint in bioproduction driving cost, supply chain risk, and delay. **The Krakatoa K500 changes that paradigm.**

Substantially Lower Media and Buffer Acquisition Cost

Powder-filled, single-use pods and on-demand production **reduces the number of consumables required, eliminates cold-chain transport, and significantly reduces incoming QC.**

Structurally Reduce Labor, Documentation, and Facility Requirements

Automated, closed, single-use workflows with integrated sterile filtration, inline monitoring, and digital batch records **remove the need for prep tanks, refrigerated storage, cleaning, and manual documentation.**

Shorten Lead Times

Produce 35–500 liters of **sterile media or buffers in as little as 3 hours** on-site and on-demand, eliminating procurement, shipping, and on-site storage.

Integrated Analytics and Digital Systems for Ease of Use

Controlled workflows, inline QC sensors for **pH, conductivity, and turbidity monitoring**, and **automatic digital batch record generation** ensure the delivery of consistent, reproducible solutions with audit-ready documentation to support GMP-compliant manufacturing for every batch.

Step Into the Future of Media and Buffer Manufacturing

Streamline your manufacturing workflow. Produce up to 500 liters of sterile cell culture media and buffers within 3 hours on-site and on-demand.

1. Insert and Connect Pod

Single-use pod is equipped with aseptic connectors and QR identification.

2. Automated Mixing

Inner bag expands and media or buffer is mixed to full volume per encoded parameters.

3. In-process Analytics

Continuous inline monitoring of pH, conductivity, and turbidity.

4. Sterile Filtration

Aseptically connected 0.2 μm filtration directly to surge bag.

5. Sample Verification

Draw analytical samples from surge bag.

6. Bioreactor

Pump sterile solution directly from surge bag into the bioreactor.



Built for Modern Biomanufacturing Organizations



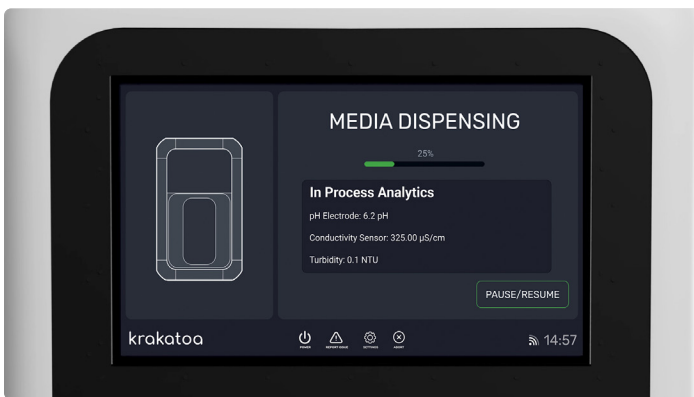
Simple by Design

- Compact, mobile design
- Fully closed, single-use system
- Simple set-up: just connect to a WFI-quality water source
- Eliminates media prep tanks and cleaning validation
- Automated solubilization and mixing of powders



Smart Automation

- **Integrated QR code** reader triggers validated processing workflow
- **Standardized recipe execution** ensures consistent solubilization and mixing of powders
- Automated system checks and diagnostics



Quality Driven

- Sterile dispensing via aseptically connected **0.2 µm filtration**
- Inline **pH, conductivity, and turbidity monitoring** during manufacture
- **Automated digital batch record generation** with time-stamped process data



Single-Use Pods and Tubing

- Prepacked, preformulated **single-use pods**
- Fully closed, **single-use fluid path** from hydration through solubilization
- Single-use set-up and no cleaning allows for **rapid turnaround**



The Power of the Pod

- Media and buffer formulations are prepackaged and delivered ready-to-use
- Two standard pod sizes that can produce any volume between:
 - 35-100 liters
 - 175-500 liters
- Up to 2-year pod shelf life (based on the component shelf life)
- QR-code-driven execution with full digital batch traceability

Krakatoa® K500 Specifications

Production Capability

Volume Range	35 L – 500 L
Total Process Time	1–3 hours (formulation dependent)
Throughput	Up to five 500 L batches per production
Volume Accuracy	±1% delivery accuracy

Single-Use by Design

Fluid Path	No internal fluid-contact surfaces
Materials	USP Class VI certified tubing, connectors, and bags that meet pharmaceutical-grade standards
Sterile Connections	Industry-standard aseptic connectors
Cleaning	None needed
Consumables	Single-use, preformulated powder pods

Instrument

Dimensions	35 in x 46 in x 68 in (W x D x H)
Weight	~750 lb
Electrical	Single-phase power, < 20 A
Voltage	110–220 VAC (60 Hz)
Gas Requirements	None
Connectivity	Ethernet, Wi-Fi, and 4G LTE fallback
Cleanroom Compatibility	ISO 8 or 7
Mobility	Heavy-duty casters for easy relocation

Consumable (Pod)

Dimensions	28 in x 28 in x 6 in
Pod Size	100 L pod – 35–100 L 500 L pod – 175–500 L
Shelf Life	2 years (based on the component shelf life)

Quality and Compliance

Compliance	21 CFR Part 11 compliant
Access Control	User-specific logins with role-based permissions
Batch Records	Automatically generated digital batch reports with timestamps
Consumable Recognition	Integrated QR code reader
Certification Status	UL/CE certified

Support and Services

Warranty	Standard 1-year warranty
Service Agreements	Optional single- or multi-year plans available
Validation Support	Qualification and validation packages offered

**The Krakatoa K500 is designed for use within validated GMP processes. Nucleus Biologics provides a comprehensive validation package (e.g., IQ/OQ/PQ) to assist customers with process qualification; however, final GMP compliance and validation of the end product remain the responsibility of the user.*