eppendorf

Unquestionable

The Enhanced Feature Set GxP for epMotion® designed to support compliance with 21 CFR Part 11, EU GMP Annex 11 and GAMP® 5 regulations.

Save Time, Gain Certainty

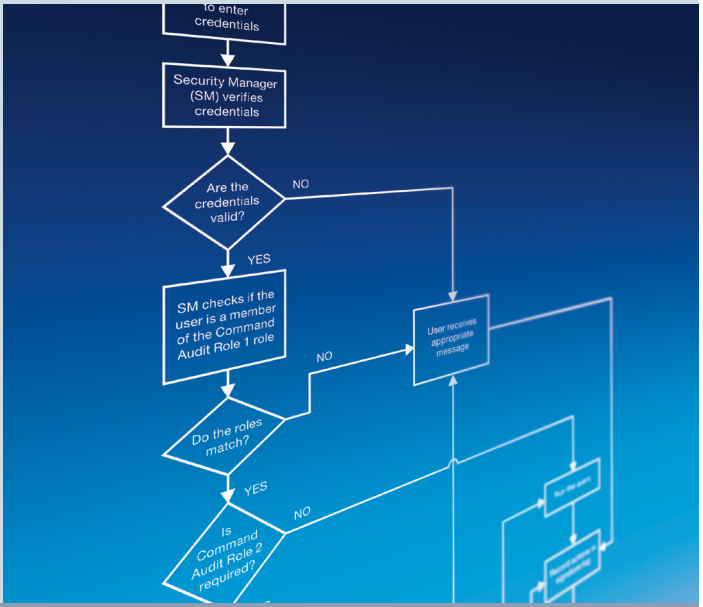
The pharmaceutical, healthcare, and medical device industries, along with related fields, must carefully consider regulatory obligations.

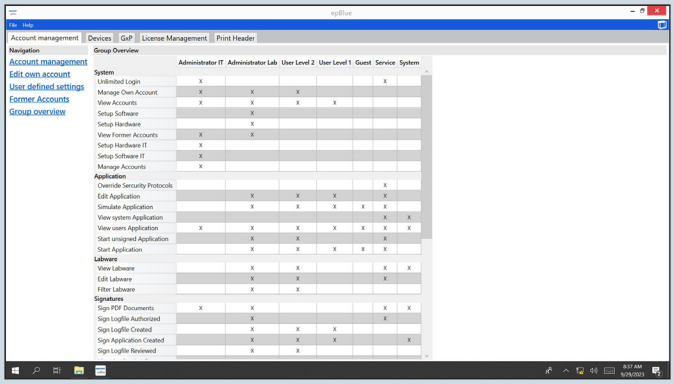
While many liquid handling procedures are getting automated for better accuracy and speed, the validation and qualification process is still time consuming and labor intensive.

Enhanced Feature Set GxP

The "Enhanced Feature Set GxP" for the epBlue software (epBlue GxP), used in conjunction with the epMotion automated liquid handling system, was developed to assist customers in achieving compliance with 21 CFR Part 11, EU GMP Annex 11, and GAMP 5.

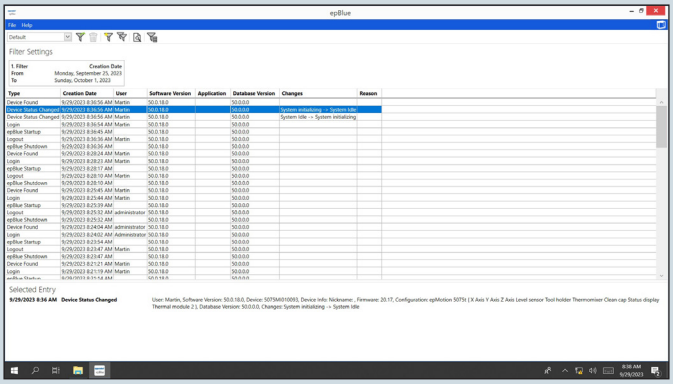
Features:
> Complete electronic documentation
> User level management & access control
> Audit trail & log file
> Revision management
> Configurable workflow management
> Electronic signatures
> Digital certificates following industry standard algorithm
> Export and archiving of digital signed documents
> Data base system
> ISO 8655 compliant dispensing tool calibration
> ID tracking using bar codes (optional extension)





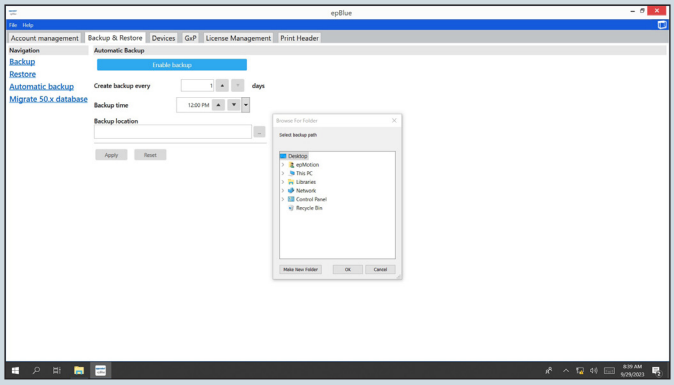
Access control

Only users with valid user ID and password can log on to create or run applications or access electronic records. Five different user levels (Admin, Admin Lab, User Level 1, User Level 2, Guest) provide flexibility to mirror a huge variety regulatory required roles and organizational set-up in your lab environment. Additional safety features such as timed locking of the application are available to prevent unauthorized access.



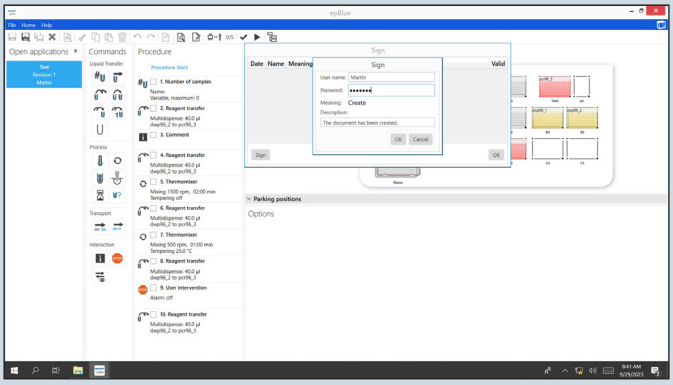
Complete electronic documentation

The epBlue GxP enables the user to create digitally signed PDFs from a huge variety types of documents, i.e. applications, log files and audit trail. Revision management of applications secures signature status (like unsigned, created, reviewed, and authorized), but keeps the flexibility to use them in a new revision later. Log files: Log of all actions of the processes on epMotion. Audit trail (figure above): All user activities are documented in an automatically generated and time-stamped audit trail. It also contains details on user administration and security violations. Apply filter settings to quickly review the details of the parts of the audit trail relevant to you.



Data security and integrity

epBlue GxP protects any generated electronic record from modifications and deletions in the data base system. Export and archive data as human readable digitally signed documents. All data contains the complete history with clear document status. Rely on industry standard digital certificates for user, system and master certificates that are easy to create for checking the electronic signatures in exported PDF documents on external computers (e.g. FDA or EMA).



Electronic signature workflow management

All important user actions need documentation and digital signatures. The workflow can be configured to request for electronic signatures at e.g. creation and review level. An executable application must follow this pre-configured workflow. A predefined user must electronically sign every step in the review cycle, before it can be passed on to the next review/workflow level. This can be easily done without log-off of previous user.

> Further information available at: www.eppendorf.com/automation

Smart solutions for labs in regulated environment

The epBlue ID is a software module that can be added to the epBlue GxP software. epBlue ID allows simple and safe data exchange with your laboratory information management system: Barcoded samples, plates and reagents will be scanned manually, their origin and destination will be recorded and documented. We also offer global certification services to support compliance with FDA 21 CFR Part 11, EU GMP Annex 11, GLP and GAMP 5 to facilitate your validation process. Explore our range of service offerings and qualification services for epMotion systems equipped with the Enhanced Feature Set GxP. Maximize the potential of your epMotion through our supportive GxP IQOQ, GxP calibration, and GxP training.

Ordering information

Description	International Order No.	North America Order No.
Enhanced Feature Set GxP. Licence for epBlue feature: GxP, for support of regulated environments (e.g. according to GLP, GMP, 21 CFR Part 11), requires service visit and epBlue 40.9 or higher	5075 002 744	5075 002 744
epBlue ID software and hardware upgrade set, for MultiCon versions (epMotion® SN > 4000), barcode support includes software, barcode reader and stand, not compatible with epMotion® panel or EasyCon versions	5075 002 701	5075 002 701

Service and Certification Plans

Description	International Order No.
IQOQ GxP - epMotion® 5070	0082 030 030
IQOQ GxP - epMotion® 5073	0082 030 031
IQOQ GxP - epMotion® 5075	0082 030 032
OQ GxP - epMotion® 5070	0082 030 040
OQ GxP - epMotion® 5073	0082 030 041
OQ GxP - epMotion® 5075	0082 030 042
GxP Calibration, 1-ch. Dispensing Tool Includes PM of the Tool, change of o-rings if required, cleaning of the tool (internal and external). Full calibration (as-found and as-left calibration). Customer will be provided with calibration report	5075 005 239
GxP Calibration, 8-ch. Dispensing Tool Includes PM of the Tool, change of o-rings if required, cleaning of the tool (internal and external). Full calibration (as-found and as-left calibration). Customer will be provided with calibration report	5075 005 247
epMotion® User Training for the Enhanced Feature Set GxP for epBlue	0082 030 026

Your local distributor: www.eppendorf.com/contact
Eppendorf SE · 22331 Hamburg · Germany
eppendorf@eppendorf.com · www.eppendorf.com

www.eppendorf.com/automation