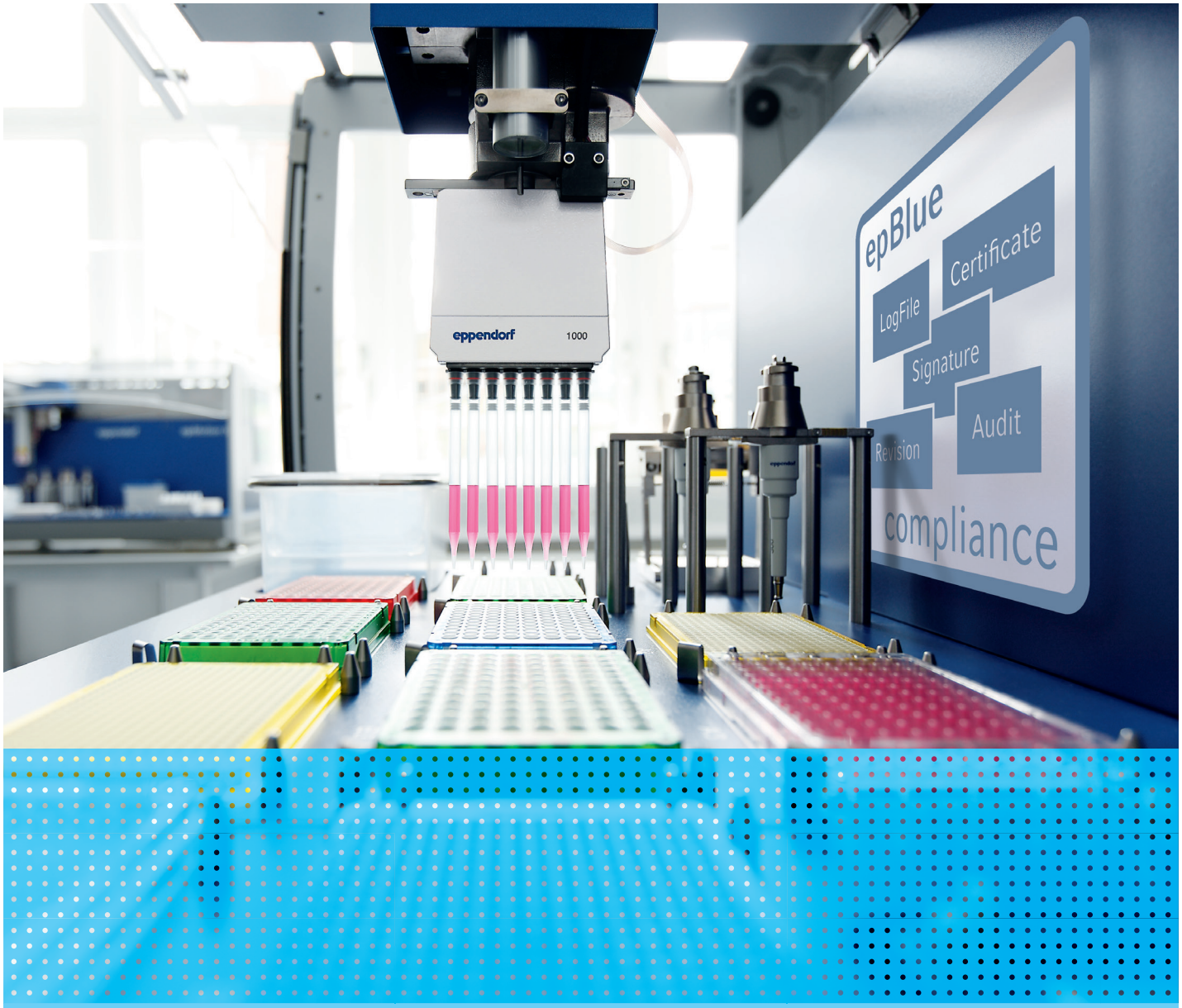
eppendorf



Unquestionable

The ep*Motion*® GxP solution for automated pipetting according to GLP, GAMP 5 and 21 CFR part 11 regulations

Save Time, gain Certainty

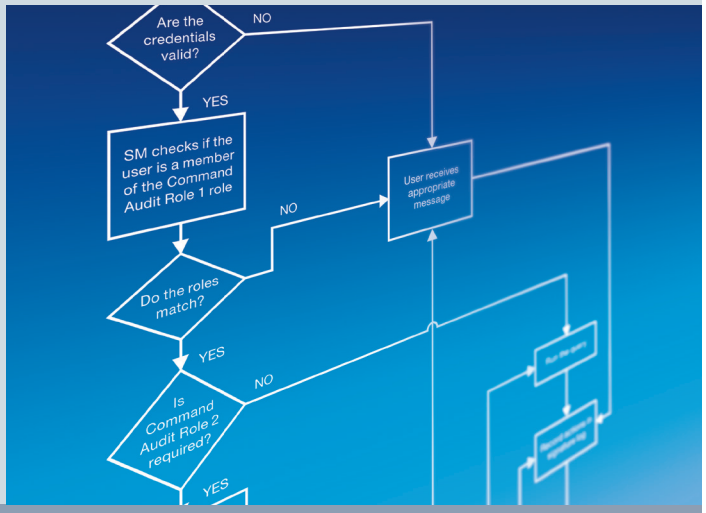
Compliance to CFR, GLP, GMP and GCP requirements is of mandatory importance for Bio- and Pharmaceutical processes and for CLIA certified laboratories.

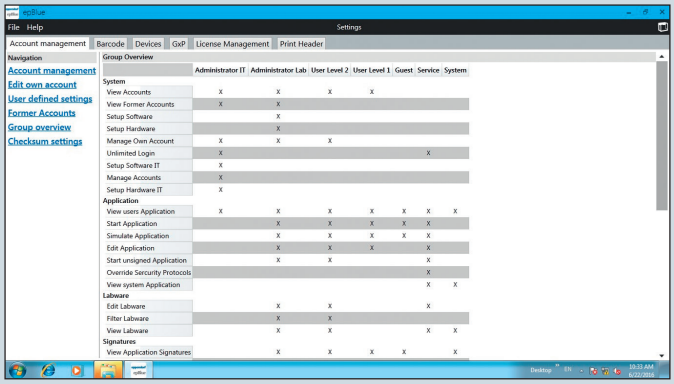
While many liquid handling procedures are getting automated for better accuracy and speed, the validation and qualification process is still time consuming and labor intensive.

ep*Motion*® GxP solution

The ep*Motion* GxP solution was developed according to GAMP 5 and tailored for organizational and process requirements of 21 CFR part 11, 58, 211 and 820, GLP, GMP and GCP. The ep*Motion* GxP solution consists of the ep*Motion* automated pipetting system, software and services that are designed to significantly shorten the timeline of your process validation and qualification. Eppendorf as supplier has already taken care of the major part of the regulatory required system validation and qualification. Thus the user can focus only on their part of the application validation.

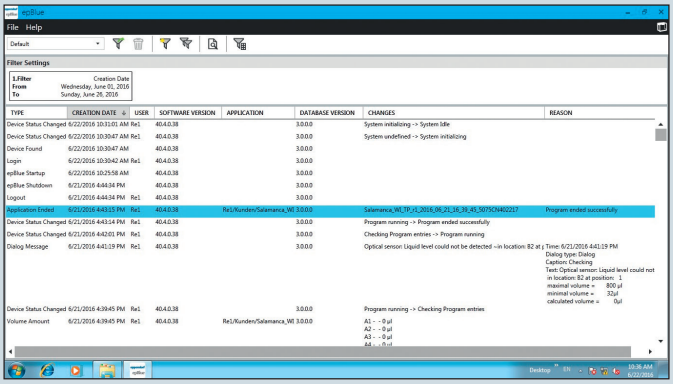
Features:
> Complete electronic documentation
> User level management & access control
> Audit trail & log file
> Revision management
> Configurable workflow management
> Electronic signatures
> Certification following industry standard algorithm
> Export and archiving of digital signed documents
> Data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





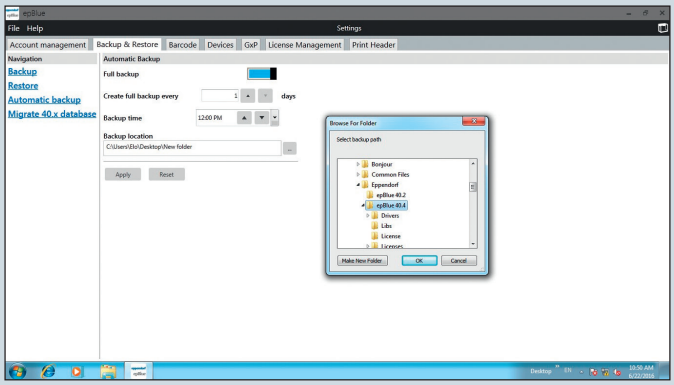
Access control

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 all 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.



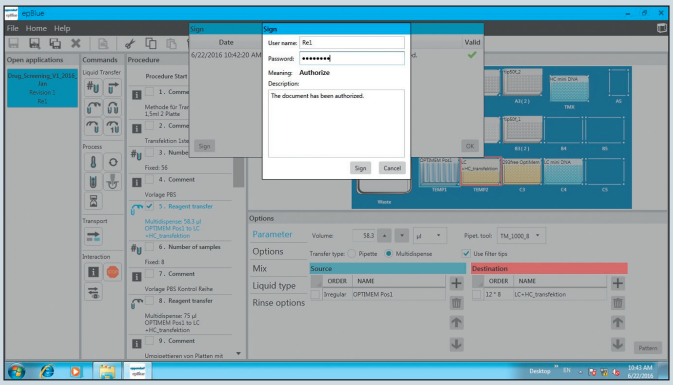
Complete electronic documentation

The epBlue GxP enables the user to create digitally signed PDF documents from all 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 easily exportable 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 if at creation and review level an electronic signature is requested. 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

Perfect solution for Labs in regulated environment

The epBlue ID is a software module that can be added to the epBlue GxP ep*Motion* PC 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 in compliance with FDA 21 CFR Part 11, EU GMP Annex 11, GLP and GAMP 5 to facilitate your validation process. We support you with different certified qualification programs for your instrument, software and personnel.

Ordering information

Description	International Order No.	North America Order No.
epBlue GxP™ software upgrade, for use in regulated process environments (according to GLP, GMP, 21 CFR), for PC versions (SN < 4000), with epBlue™ GxP software, corresponding firmware, USB hardware key, certificates. Not compatible with ep*Motion*® panel or EasyCon versions	5075 000.849	5075000849
epBlue GxP™ software upgrade, for use in regulated process environments (according to GLP, GMP, 21 CFR), for MultiCon versions (ep*Motion*® SN > 4000), with epBlue™ GxP software, corresponding firmware, certificates. Not compatible with ep*Motion*® panel or EasyCon versions	5075 002.728	5075002728
epBlue ID™ barcode software module, extension for epBlue and epBlue GxP to support barcode based documentation and work listing. Includes manual barcode reader and barcode reader stand. The epBlue ID module is compatible with all eep*Motion*® GxP versions	5075 002.000	5075002000
epBlue ID™ software and hardware upgrade set, for MultiCon versions (ep*Motion*® SN > 4000), barcode support includes software, barcode reader and stand, not compatible with ep*Motion*® panel or EasyCon versions	5075 002.701	5075002701

Certification Plans	BASIC	STANDARD	PREMIUM
Order Number	5075 005.182	5075 005.190	5075 005.204
Installation and Operational Qualification (IQ/OQ): according to Eppendorf SOPs incl. 1 single and 1 × 8-channel dispensing tool calibration (according ISO 8655), complete documentation and certificates	■	■	■
ep*Motion*®/epBlue™ User Starter Training: incl. training documents and certificates	■	■	■
ep*Motion*® GxP User, Administrator Lab and Administrator IT Training:	■	■	■
Lab Automation Seminar/Workshop: incl. training documents and certificates at Eppendorf Training Center - one person. ep*Motion*® basics incl. training documents and certificates		■	■
ep*Motion*® GxP Seminar/Workshop: one person. Electronic signatures, audit trail, Barcode ID, archiving, administrator functions (21 CFR Part 11, GAMP 5) incl. training documents and certificates			■
ep*Motion*® Application Support: customized one day support (e.g. support with customer method programming)			■

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