QM/QS

QM/QS includes the following functions:

- Batch tracing
- Protocols
- Product specifications and certificates
- Clearance, versioning
- LIMS, analysis data, statistics
- Safety data sheets
- Stability database
- Maintenance planning

Batch tracing

Thanks to the comprehensive logging of all movements comprising the relevant information, the Inventory Information System answers a series of questions in the twinkling of an eye, as the following example from PPS Batch Tracing illustrates:

- Which customer was the batch shipped to?
- When was the batch produced?
- Show the production log of the batch.
- Which raw material batches have been used for production?
- Who supplied said raw material?
- When was the raw material supplied?
- Show the protocol of the incoming goods inspection.
- For which other products has the same raw material batch been used?
- To which customers have the final products already been shipped?

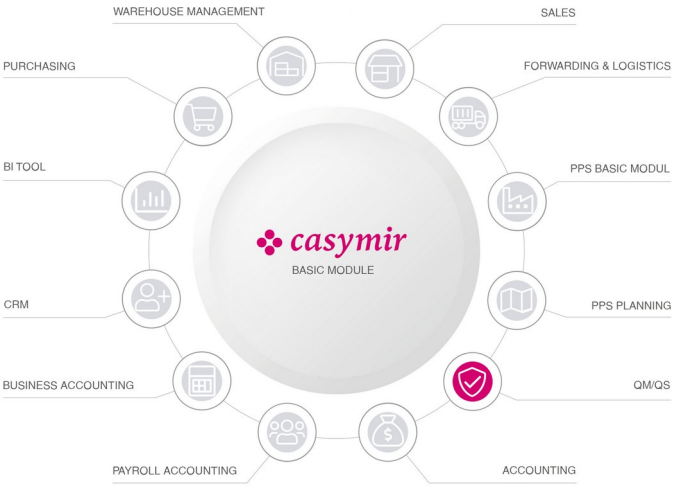
Integration with PPS basic module

The CASYMIR QM/QS area is strongly interlinked with the production modules. You will find further information on the following subjects in our PPS brochure:

- Logging
- Product specifications, certificates
- Clearance, versioning
- LIMS, analysis data, statistics

Safety Data Sheets

Safety Data Sheets (SDS) or Material Safety Data Sheets (MSDS) are an instrument of communication of safety-relevant information on substances and mixtures, including information from the chemical safety reports on the supply chain to the downstream user.



The structure and content of Safety Data Sheets is established and arranged in detailed by the REACH regulation.

Once configured, Safety Data Sheets can be produced at the touch of a button.

Stability Database

Especially in the chemical and pharmaceutical industry, short and long-term monitoring of product stability and properties is of utmost importance.
It is thus an essential part of quality management. In order to support users in this extensive task, we have implemented a Stability Database Module in CASYMIR. The CASYMIR Stability Database is especially suitable for use in production companies from different sectors. The system offers special support for GMP-compliant operations, particularly in the chemical and pharmaceutical industry.

Stability plans

Stability plans form the basis for working with the database. They describe checks to be carried out even over longer periods of time (e.g. 5 years / 10 years) and include, among others, process instructions, measurements, storage conditions and time patterns. The stability database also supports users by administrating test samples. For example, it determines how many samples of an article or a batch must be provided for inspections.

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Sample plans

Work with the stability database module starts with the creation of a sample plan. It includes, partly automatically:

- action types (type of measurement)
- biological
- chemical
- physical
- organoleptic
- actions (kind of measurement)
- analyses of whatever kind, e.g. colour identification, odour determination, density, sponification number, refractive index, acid value, bacterial count, etc.
- Parameter names (environment dimensions)
- up to 5 basic parameter dimensions for all stability projects
- e.g. light influence, storage position, temperature / humidity, packaging
- Parameter (environmental conditions)
- A series of parameters serves to determine the specification of the parameters
- A stability project can include evaluations under different environmental conditions at the same time
- light: normal light-dark changes
- storage position: standing on the cap
- packaging: original packaging or similar to original container
- Temperature / humidity: e.g. 4°C (refrigerator), 20°C /60% (room temperature), –20°C
- (deep freezer), 40°C /20% (incubator), 40°C /80% (incubator).

Basic data

The necessary basic data are included via master data entry, which allows the user to define any number of:

- action types (type of measurement)
- biological
- chemical
- physical
- organoleptic
- actions (kind of measurement)
- analyses of whatever kind, e.g. colour identification, odour determination, density, sponification number, refractive index, acid value, bacterial count, etc.
- Parameter names (environment dimensions)
- up to 5 basic parameter dimensions for all stability projects
- e.g. light influence, storage position, temperature / humidity, packaging
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Timeline

After the sample plan for the monitoring of an article or a batch has been established, the system automatically generates:

- a timeline and the number or required specimens
- a to-do list with indications on which measurement has to be carried out at which time
- a pre-view of the pending measurements and checks within a freely definable period
- a table in which the date and the corresponding measurement values can be registered and commented
- instructions on what to do if measurements are not within the defined boundaries

The data registered in the automatically generated time lines can be modified manually if necessary and allowed. In this case, the system generates a new line at the push of a button.

The data registered in the generates measurement tables can be exported for further use, e.g. in statistical evaluations.

All actions and measurements are logged in a way that complies with the requirements of modern quality assurance systems.

The following evaluations are possible at any time:

- analysis value lists, retrospective, forward or for the future
- working papers, e.g. for the day's work
- detailed excerpt for all stored data

Interfaces

- Export of specifications in different formats (PDF, XML, and others)
- Export of production orders, recipes from master computers to production plants
- Export of machine setups to production machines
- Import of operating data from production plants
- Balance interface
- Export of stability measurement data

Settings

Configuration via the registration of master data. Numerous configuration options via system configuration and customizing function.

Standards and requirement

- German Medicines act (AMG), Pharmaceuticals and Active Agent Manufacturing Ordinance (AMWHV)
- EU GMP guidelines, EMEA guidelines, ICH guidelines
- 21 CFR Part 11 and cGMP standards by the FDA
- British Retail Consortium (BRC)
- Commission Regulation (EC) No 178/2002 – General Principles and Requirements of Food Law
- EU regulation 1935/2004 on materials and articles intended to come into contact with food
- International Food Standard (IFS)
- ISO 22000:2005
- German Food Labelling Ordinance (Lebensmittelkennzeichnungsverordnung)
- German Food Hygiene Ordinance (Lebensmittelhygieneverordnung)
- HACCP concept
- REACH (Registration, Evaluation and Authorisation of Chemicals)
- GHS (Globally Harmonized System)
- German Chemicals Act (ChemG) and Ordinance on Hazardous Substances (GefStoffV)