FREY&LAU

explore your senses

Pharmaceuticals

Agent Meeting 2023

The FREY&LAU QA Department

ONE TEAM – HIGH KNOWLEDGE

- One Quality Assurance team
- 12 highly qualified QA experts with a large expertise
- Different specialization
- Many years of professional experience

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- Master in Nutrition and Food Quality Management
- Food Technology and Economy with special knowledge of Food Processing
- Food Technology with master's degree
- Food Chemist
- Industrial Clerk with additional qualification for Business Assistance
- Diploma Ecotrophologist and Wholesale Clerk
- Ecotrophology with bachelor's degree
- Wholesale and Foreign Trade Clerk
- M. Sc. Bioprocess Engineering
- Pharmacists

The FREY&LAU QA Department

RESPONSIBILITIES

One team in charge of all topics and tasks of essential oils, flavours, fragrances and aroma chemicals.

- Depending on the topic and complexity, the tasks are executed by respective specialists or by a team
- From natural cosmetics to active pharmaceutical ingredients (API) for the pharmaceutical industry

One area of particular importance: Pharmaceuticals

- QA is involved in all activities from the beginning until the end of the supply chain, e.g. supplier release, supervision of production process and batch release, guidelines and specifications and regulatory affairs.

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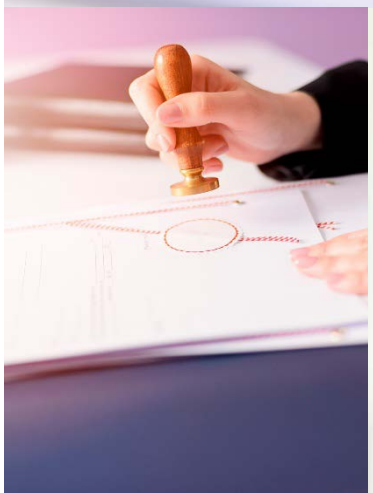
OUR QMS INCLUDES ALL REQUIREMENTS FOR PHARMACEUTICAL PRODUCTS

- EU GMP Guideline for API
  - Annex 7
- Overall GMP rules and regulations
- ICH guidelines
- WHO guidelines

- Manufacturing Licence
- GMP certificate



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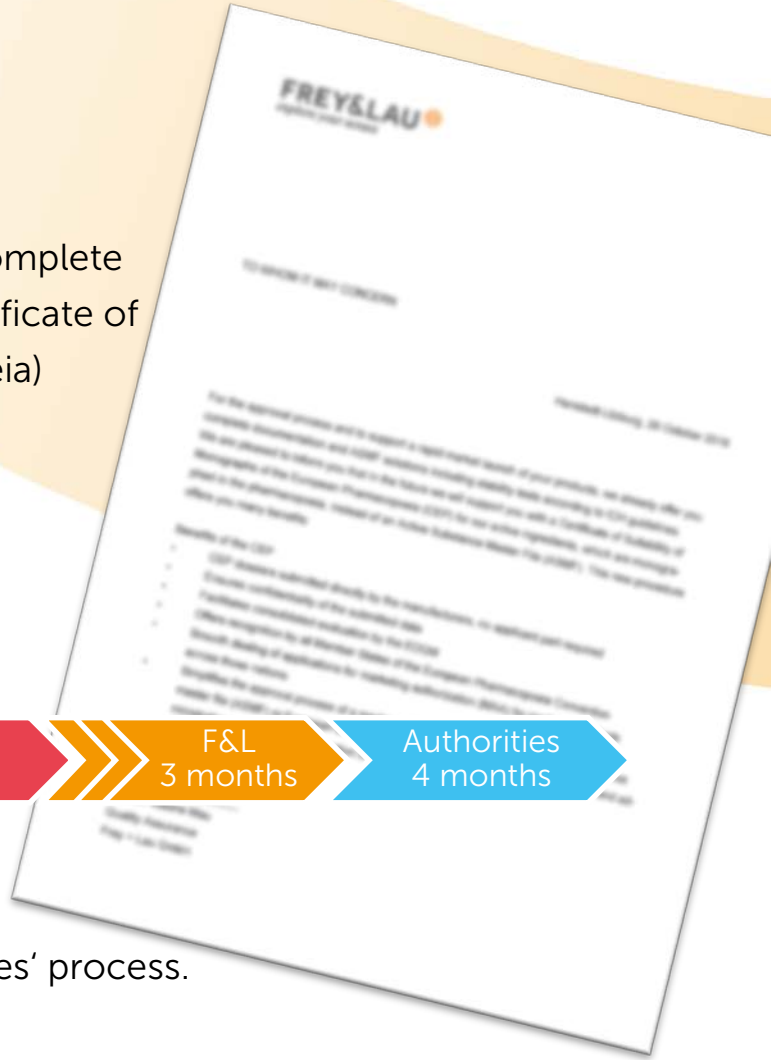
The FREY&LAU CEP Fokus

REGULATORY AFFAIRS

Response to technical questions and questionnaires up to complete dossiers as **ASMF** (Active Substance Master File) or **CEP** (Certificate of Suitability to the monographs of the European Pharmacopoeia)

- What is required for a pharmaceutical dossier?
- **Effort varying up to several weeks!**



The time-consuming process for CEP:

We can speed up the in-house process, but not the authorities' process.

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Quality
is the heart
of everything.

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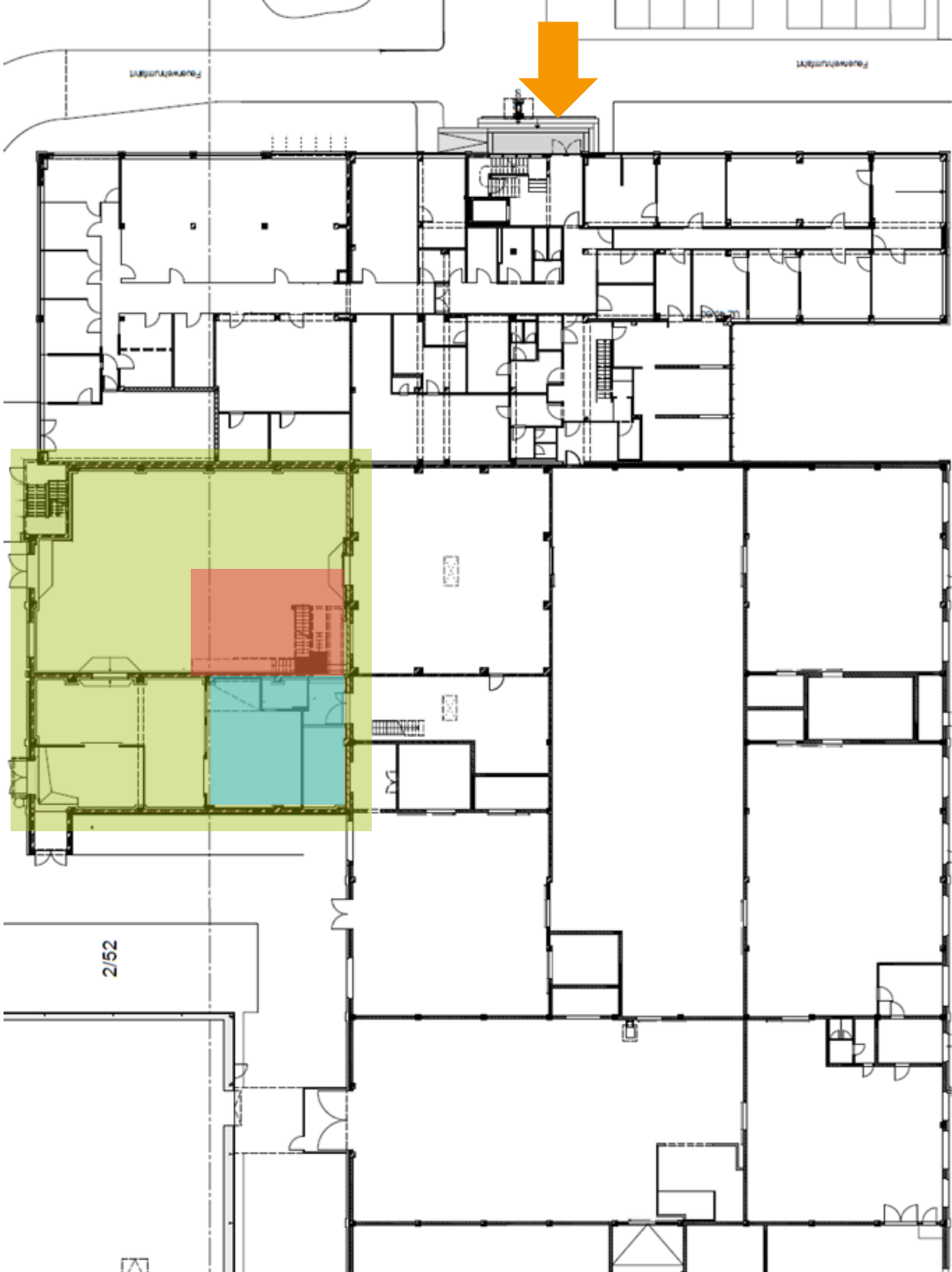
New Premisses

OVERVIEW OF PRODUCTION AREA INCLUDING NEW GMP AREA

- → Main entrance
- → New production area
- → New distillation unit
- → New GMP area



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Our New GMP Area

NEW PREMISSES

- New GMP area in operation since Feb 2019
- Inspection by the GMP-Inspection-Authority, State Social Services Agency (Landesamt für soziale Dienste Schleswig-Holstein) in Oct 2018
- Approval by the authority on 4th of Feb 2019

500qm^2 additional production area complying to pharmaceutical GMP-Standard

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Our new Distillation Unit

WITH NEW GMP-AREA

- Investment of 5 million Euro
- Applicable for all areas
- Capability to remove undesired compounds by distillation
- Backup for the production of rectified eucalyptus oil from crude oil to prevent a possible supply breakdown
- Installation: May 2018
- Launch: January 2019
- 13,5 meters high, 30 tons heavy
- Increase of our distillation capacity by 40 %
- High-precision fractionation of crude oils

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Our Products

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Supply Chain Overview

STARTING ON THE FIELD

A – Everything starts in the country of origin:

- Cultivation of the medicinal plant
- Harvest of the herbal drug and extraction by water steam distillation close to the fields -> crude essential oil
- For some of the products: additional distillation under GMP -> rectified essential oil

B – Shipment

- Filling of the essential oil into suitable containers, e.g. drums
- Transportation by truck/ship from the country of origin to FREY&LAU

C – Arrival at Frey + Lau

- Incoming goods control and testing according to specification
- Further processing steps, e.g. rectification, homogenisation, etc.

GACP

GMP

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Registration // ASMF // CEPs

ASMF/CEP-STATUS OF THE GMP OILS

ASMF/CEP-status	GMP oils
GACP concept complete	Cassia oil, Cineole/Eucalyptol, Clove oil, Eucalyptus oil, Lavender oil, Levomenthol, Mint oil, Peppermint oil, Rosemary oil, Spike Lavender oil, Tea Tree oil, Thyme oil, Turpentine oil
GACP concept possible (without much effort)	Fir needle oil, Dwarf Pine oil

Registration // ASMF // CEPs

CEP STATUS

GMP oils	CEP status
Cineole	available
Clove oil	available
Eucalyptus oil	available
Lavender oil	available
Levomenthol	available
Mint oil	available
Peppermint oil	available
Rosemary oil	available
Spike Lavender oil	available
Thyme oil	available
Turpentine oil	available
Cassia oil	expected
Tea Tree oil	expected
...and others in progress!	

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Presentation of Our APIs

OUR PRODUCT LIST

- Table of all APIs
  - Essential oils
  - Aromachemicals
- GMP status, all GMP suppliers are auditited every 3 years
- Third Party Audits used for suppliers and also for FREY&LAU
- Written confirmation available where required

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Product list Active Pharmaceutical Ingredients (API)

Product	Documents for Marketing Authorization	Monograph
Camphor rac.**	CEP + ASMF	Ph. Eur.
Cassia oil, rect.	ASMF	Ph. Eur.
Clove oil, rect.	CEP + ASMF	Ph. Eur.
Dwarf pine oil, rect.	ASMF	Ph. Eur.
Eucalyptol/Cineole	CEP + ASMF	Ph. Eur.
Eucalyptol/Cineole, dried	CEP + ASMF	Ph. Eur.
Eucalyptus oil 80%, rect.*	CEP + ASMF	Ph. Eur.
Eucalyptus oil 80%, double rect.*	CEP + ASMF	Ph. Eur.
Eucalyptus oil 70%, rect.*	CEP + ASMF	Ph. Eur.
Fennel oil, bitter, rect.	–	Ph. Eur.
Fir needle oil, rect.	ASMF	DAB / FP
Lavender oil, rect.	CEP + ASMF	Ph. Eur.
Levomenthol	CEP + ASMF	Ph. Eur.
Methyl Salicylate	–	Ph. Eur.
Mint oil, partly dem., rekt*	CEP + ASMF	Ph. Eur.
Mint oil, partly dem., double rect.	CEP + ASMF	Ph. Eur.
Peppermint oil, rect.	CEP + ASMF	Ph. Eur.
Peppermint oil, double rect.	CEP + ASMF	Ph. Eur.
Pine needle oil, rect.	ASMF	DAB
Pine needle oil, rect.	–	Ph. Eur.
Rosemary oil, tunes./maroc., rect.	CEP + ASMF	Ph. Eur.
Spike lavender oil, rect.	CEP + ASMF	Ph. Eur.
Star anise oil, rect.	–	Ph. Eur.
Tea tree oil, rect.	ASMF	Ph. Eur.
Tea tree oil, rect. methyleugenolred.	ASMF	Ph. Eur.
Thyme oil, rect	CEP + ASMF	Ph. Eur.
Thymol**	–	Ph. Eur.
Turpentine oil, rect.*	CEP + ASMF	Ph. Eur.

The above listed articles are produced in our GMP area according to the valid EU GMP guidelines.
They are part of our EGST product line and can be used as active pharmaceutical ingredients.
* Defined in the monograph as rectified essential oils.
** Camphor, Methyl Salicylate and Thymol are manufactured by chemical processes.
CEP: Certificate of Suitability; granted by EDQM
ASMF: Active Substance Master File

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New APIs

PLANNING POINT

Projects – already started:

- Cassia oil
- Majoram oil
- Wintergreen oil

Approximate costs of a new pharmaceutical product:

- 60.000 € if already present as conventional product
- 200.000 € if completely new

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Substances used as APIs

OUTSIDE EU AND WITHIN EU DIFFERENT REQUIREMENTS AND REGULATIONS

Despite harmonization of many regulations inside and outside the EU

- Used by customer as API -> possible according to regulations
- At F+L manufactured according to Food and Cosmetic guidelines, not handled in the GMP area
- In EU compliance with requirements of excipients
- Documentation according to Food and Cosmetics guidelines available
- Depending on the region the suitability may be different
- Customer decides whether it can be used for its purposes

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