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WHITE PAPER

SAFE AND EFFICIENT HANDLING OF HIGH POTENT DRUG PRODUCTS

A holistic concept

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1 HIGH POTENT APIs: A DEFINITION

1 Potency und toxicology

High potent APIs (HPAPIs) are characterized by their pharmacological potency and toxicological properties.

Pharmacological potency describes the drug effect vs. the dose of an API required to induce the respective pharmacological effect. A drug substance with a high potency induces a high effect at low dose. This correlation, however, is not sufficient to comprehensively classify HPAPIs.

> For a precise definition of HPAPIs the toxicological characteristics are the measure of choice.

2 The toxicological properties of high potent active ingredients

The toxicity of a substance refers to the harmful effects that they can cause in humans. The decisive factor is the quantity or concentration of the substance in question. As already handed down by Paracelsus, “All things are poison, and nothing is without poison; it is only the dose that makes a thing not a poison”.[1]

3 Classification of HPAPIs

The toxicological properties require a health-based risk management for the handling of active ingredient at the workplace in order to ensure optimal employee protection on the one hand and to exclude a negative impact on other products, i.e., via cross-contamination, on the other hand.

In the pharmaceutical industry an Occupational Exposure Banding (OEB) developed by the U.S. National Institute for Occupational Safety and Health (NIOSH) [2] is used to assign chemicals into specific categories. It is an important instrument for the hierarchical structure of Occupational Exposure Limits (OEL).

An OEL is the upper limit on the acceptable concentration of a hazardous substance in workplace air (in µg/m^3). It is set to prevent occupational diseases to workers.

Currently, there is no international harmonized standard for the definition of an HPAPI because classification systems vary across regions and companies. HPAPIs are mainly characterizes by A and B. Besides, toxicology professionals consider also factors such as C to E:

A OEL <10 µg/m^3

B Therapeutic daily dose <10 µg per kg body weight

C Cancerogenic, mutagenic or toxic for reproduction (CRM) characteristics

D APIs with high selectivity (e.g., enzyme inhibitors), potent sensitizers (e.g., ß-Lactam-antibiotics)

E Severe acute toxicity

OEB Categorization describes classes of risk with guidance on the handling of compounds attributed to the respective class.

[1] Sudhoff-Ausgabe, Band XI, R. Oldenbourg, München und Berlin (1928), S. 123–160: Sieben Defensiones 1537/38, S. 138. https://publikationsserver.tu-braunschweig.de/rsc/viewer/dbbs_derivate_00000699/max/00000177.jpg

[2] NIOSH [2019]. Technical report: The NIOSH occupational exposure banding process for chemical risk management. By Lentz TJ, Seaton M, Rane P, Gilbert SJ, McKernan LT, Whittaker C. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS

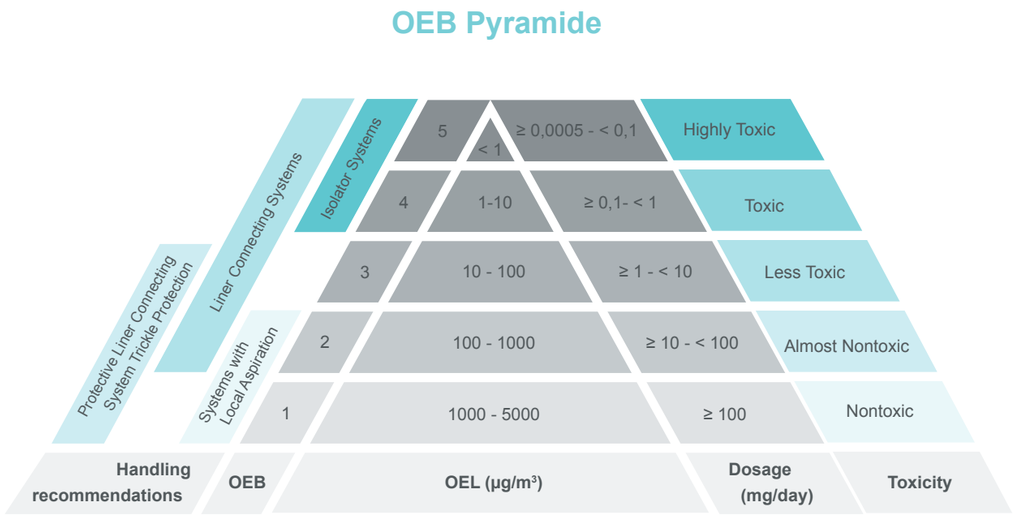


Figure 1 Overview of OEB, OEL and potency of compounds (Graphic: Aenova Group) [3]

Figure 1 gives also a high-level guidance on handling requirements appropriate for a certain OEB. It is recommended that certain classes of active ingredients should be manufactured in dedicated or specifically equipped facilities.

In previous EU GMP regulations, certain product groups were circumscribed as HPAPIs, such as “certain antibiotics, certain hormones and certain cytotoxics”, linked with the demand to produce them in dedicated facilities only.

In the current EU GMP regulations, the stigmatisation of these HPAPIs groups is largely removed and replaced by a scientific risk-based approach that incorporates API specific acceptable daily exposure limit. This creates a more straightforward pathway for “shared” facilities based on a holistic production concept.

The underlying concepts and requirements for handling HPAPIs and consequently serve current market needs are elaborated in the following chapters.

4 Therapeutic indications of high potent APIs

Drugs with high potent active ingredients aim at central, life-saving and life-enhancing therapies in various fields of application.

These include mainly

- Oncology: cytotoxic or cytostatic drugs and novel specific pathway inhibiting compounds
- Immunosuppressants
- Hormone therapy / endocrine therapies

The development of more and more innovative high potent drugs is progressing rapidly. At the same time, patents of innovators are expiring, leading to an increased demand in the generic market of high potent drugs.

According to the Anatomical Therapeutic Chemical (ATC) Classification System, which is the international standard for therapeutic classes, HPAPIs are mainly included in the classes listed in table 1.

[3] Graphic adapted from NIOSH https://wwwn.cdc.gov/Niosh-oeb/

Therapeutic class	ATC2	ATC3
Oncology and Immunosuppressants	L1 Antineoplastics	L1A Alkylating Agents
		L1B Antimetabolites
		L1C Plant-based Antineoplastics
		L1D Antineoplastic Antibiotics
		L1H Protein Kinase Inhibitor Antineoplastics
		L1J Proteasome Inhibitor Antineoplastics
		L1X all other Antineoplastics
	L2 Cytostatic Hormone Therapy	L2A Cytostatic Hormones
		L2B Cytostatic Hormone Antagonists
	L4 Immunosuppressants	L4X other Immunosuppressants
Sex Hormones	G3 Sex Hormones-Systemic	G3A Hormonal Contraceptives, systemic
		G3B Androgens, excl. G3E, G3F
		G3C Oestrogens, excl. G3A, G3E, G3F
		G3D Progestogens, excl. G3A, G3F
		G3E Androgen + Female Hormones
		G3F Oestrogens + Progestogens
		G3G Gonadotrophins
		G3J SERMs
		G3X other Sex Hormones and similar

Table 1: HPAPIs according to the Anatomical Therapeutic Chemical (ATC) Classification System [4]

In pharmacotherapy of the above-named indications, solid dosage forms are the preferred dosage form. Solid dosage forms, in contrast to e.g., injectables, offer the advantage of highest patient adherence to treatment, as well as ideal stability properties and efficiency in distribution world-wide.

> Consequently, handling of high potent solid dosage forms is a key need of current pharmaceutical development and manufacturing.

[4] https://www.ephmra.org/sites/default/files/2022-01/2022%20ATC%20Guidelines.pdf

5 Market development of HPAPI containing solid dosage forms

Oncology and hormone therapy have gained increasing importance in the last decade, as innovation in drug research allowed to develop more and more target specific substances. These active substances exhibit an improved risk-benefit profile (higher therapeutic efficacy and lower adverse effects). Consequently, HPAPIs will play an important role in drug therapy in the future.

Notably, the WHO International Agency for Research on Cancer predicts an increase of new cancer cases up to 30,2 million in 2040.[5]

Based on this tremendous medical need more than 1.000 high-potent drug candidates are in research and development and a yearly growth of 10% is predicted.

Towards a comprehensive analysis, we structured the solid dosage form HPAPI market by four Anatomic Therapeutic Chemical (ATC) codes, which are summarized in table 2. The figures therein clearly indicate that the solid dosage form HPAPI market shows constant growth for L1 Antineoplastics, L2 Cytostatic Hormones and L4 Immunosuppressants. With 73% G3 Sex Hormones-Systemic have the highest market share but stagnated in volume over the last three years.

L2 Cytostatic Hormone Therapy shows a 3-year compound annual growth rate (CAGR) of +4,1%, and L1 Antineoplastics increased with highest 3-year-CAGR +7,3%.

28% of L1 Antineoplastics' volume are Protein Kinase Inhibitor Antineoplastics (L1H) and grew +18,5% in a 3-year-CAGR with 84 molecules (including 10 new APIs with sales in 2021). 40 L1H-molecules show a 3-year-CAGR above +10%. Largest L1 ATC is L1B Antimetabolites (52%) that increased +2,4% in a 3-year-CAGR.

HPAPI ATC-2-codes	Solid HP-API volume shares 2021 % (Counting Units)	3-year-CAGR (2019-2021)
L1 Antineoplastics	7%	+ 7,3%
L2 Cytostatic Hormone Therapy	7%	+ 4,1%
L4 Immunosuppressants	13%	+ 3,4%
G3 Sex Hormones-Systemic	73%	- 0,5%

Table 2: Market growth for ATC L1, L2, L4 und G[6]

[5] CANCERTOMORROW, International Agency for Research on Cancer (IARC, WHO), https://gco.iarc.fr/tomorrow/en/dataviz/isotype?sexes=0&single_unit=500000, website visited 7th July 2022

[6] Source: IQVIA MIDAS 2019-2021, High Potent market definition by Aenova (solid HPAPIs of ATC: L1, L2, L4X, G3)

L2 Cytostatic Hormone Therapy

L2 Cytostatic Hormone Therapy (+4,1%) showed a positive development in the 3-year period, albeit with somewhat lower growth rates. L2 consists of 24 APIs, 2 new APIs with sales in 2021. Darolutamide (+612%) and Apalutamide (+154%) showed very strong growth rates, even if volumes in both cases were not yet as high as of leading APIs like Tamoxifen, Letrozole or Anastrozole.

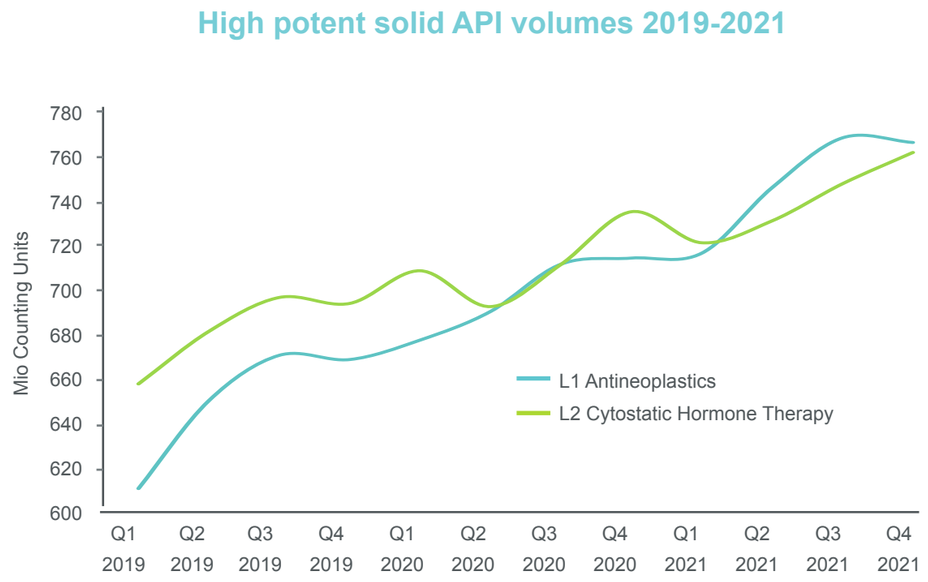


Figure 2 High Potent solid API volumes 2019-2021 of L1 Antineoplastics, L2 Cytostatic Hormone Therapy [7]

Capacity Expansion for High Potent APIs

Novel production building at Aenova Regensburg:

- > 1.000m² of state-of-the-art HPAPI production capacities
- Including bulk and packaging capabilities
- Offering customer-specific 'plant-in-plant' option
- Lean state-of-the-art QC laboratories
- Expanding HPAPI pilot plant & development capacities

[7] Source: IQVIA MIDAS 2019-2021, High Potent market definition by Aenova (solid HPAPIs of ATC: L1, L2, L4X, G3)

L4X Other immunosuppressants

L4X Other Immunosuppressants is the third strongest growth driver of all solid HPAPI ATC classes.

Tacrolimus, Mycophenolate Mofetil, Azathioprine and Ciclosporin cover 80% of ATC-3: L4X other Immunosuppressants (+3.4%) volumes. Upadacitinib is an innovative immunosuppressant molecule with highest volume increase since 2020.

High potent solid API volumes 2019-2021 of L4X Other Immunosuppressants

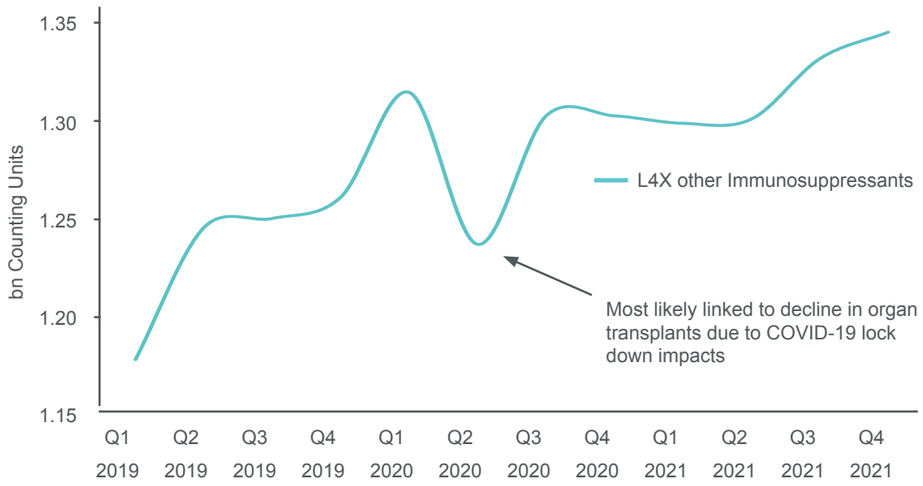


Figure 3 High Potent solid API volumes 2019-2021 of L4X Other Immunosuppressants [8]

In summary this market analysis shows an utmost need to serve the increasing demand of manufacturing and developing of high potent products. Volumes of available products are ramping up and innovative new products are entering the market.

To support this development, scalable state of the art pharmaceutical manufacturing and development capacity, as well as expert know-how in handling HPAPIs are required.

In the next chapters we describe how a holistic approach to serve the market demands looks like and how choosing the right service provider for HP products makes a difference.

[8] Source: IQVIA MIDAS 2019-2021, High Potent market definition by Aenova (solid HPAPIs of ATC: L1, L2, L4X, G3)

2 SAFE AND EFFICIENT HANDLING OF HPAPIs

Many pharmaceutical companies are outsourcing the development and especially the production of high potent drugs to CDMOs. According to a recent study by PriceWaterhouseCoopers, this trend of resource optimisation and risk reduction will continue in the coming years.[9]

As many molecules in the above indication areas are in preclinical- or clinical trial-phase, the inherent safety and toxicity issues pose a particular challenge for future commercial production.

The development and production of drugs with high potent active ingredients is highly complex and often must be implemented with acceleration. This is because many of these new molecular entities (NMEs) are developed in a fast-track manner as “breakthrough therapy” and are intended to meet medical needs quickly. For such scenarios, reliable and experienced partners are urgently required.

Holistic concept for safe and efficient handling of HPAPIs

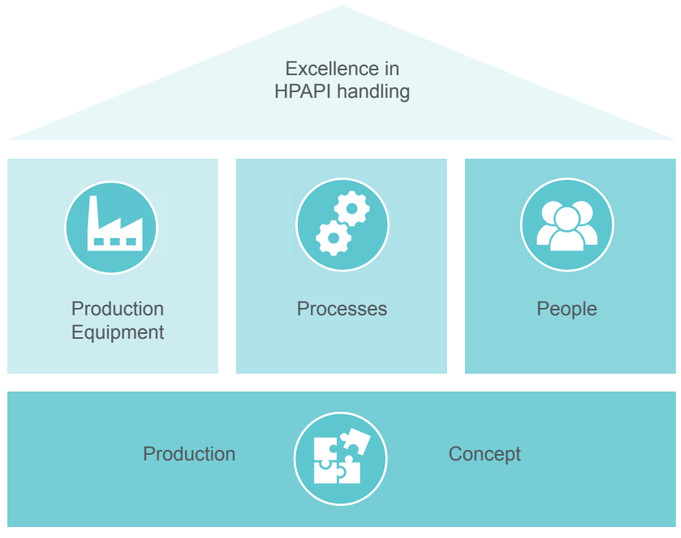


Figure 4 An intelligent and efficient production concept ensures Excellence in HPAPI handling (Graphic: Aenova Group)

But what are the right criteria for finding a suitable CDMO? In any case, it is not enough to have the facilities and capacities alone. The decisive factor here is an intelligent, efficient and well-founded - and thus holistic - production concept. Based on this the pillars, production equipment, people and processes build a sustainable foundation for the Excellence in HPAPI handling.

[9] PriceWaterhouseCoopers 2022 Global CDMO Study of Pharmaceutical Operations https://www.strategyand.pwc.com/de/en/industries/health/2022-global-cdmo-study.html

1 Production concept

Dealing with HPAPIs and the manufacturing of high potent medicinal products is challenging. This turned already out in course of the previous definition of HPAPI.

The regulatory requirements to produce HP drugs, which are laid down in various international guidelines, are consequently high and strict, e.g.:

- EU GMP guideline chapter 3 and 5, Annex 15
- Verification test acc. ISPE/SMEPAC for implementation of new equipment
- Further regulations, most important:
  - PIC/S, CFR 211,167 Equipment Cleaning and Maintenance
  - FDA Guide to Inspection Validation of Cleaning Processes
  - Niosh (National Institute for Occupational Safety and Health) regulations
  - Risk based Map ISPE Vol. 7 Decision: Dedicated equipment – multi-product facility

The manufacturer must consider various topics to meet these regulatory requirements:

- Risk management in collaboration with occupational toxicologists, especially in case of introduction of new APIs
- Plant security, containment concept
- Cleaning validation, cleaning concept
- Product segregation (dedicated or shared facilities)
- Building-, room- and HVAC- design
- Properly equipped laboratories
- Highly qualified and well-trained personnel

It should be emphasised again that a manufacturer with HPAPI's expertise must not only have the appropriate equipment, containment devices and material flows, but must also employ appropriately experienced and trained personnel across all the departments involved. This includes a comprehensive training concept and the right "mind set" of the staff.

An optimally suited **P**roduction concept is therefore the basis for a well-designed interaction of **P**roduction equipment**, P**rocesses and **P**eople.

The implementation and smart combination of these elements forms a holistic production concept which is the basis for the successful handling of HPAPIs.

2 Production equipment

Basically, the essential first pillar of the production concept is the production equipment and its required grade of containment.

Closed systems such as isolators are state-of-the-art and offer the maximum safety for the personnel and the quality of the product. However, the investment strategy required for this, and the handling of the infrastructure should not be underestimated.

Besides a precise process analysis, they require a detailed risk analysis to determine the plant design with the appropriate degree of containment.

The holistic production concept for the entire manufacturing process is crucial. In addition apart from the potency or toxicity of the active ingredient, further factors must be taken into account.

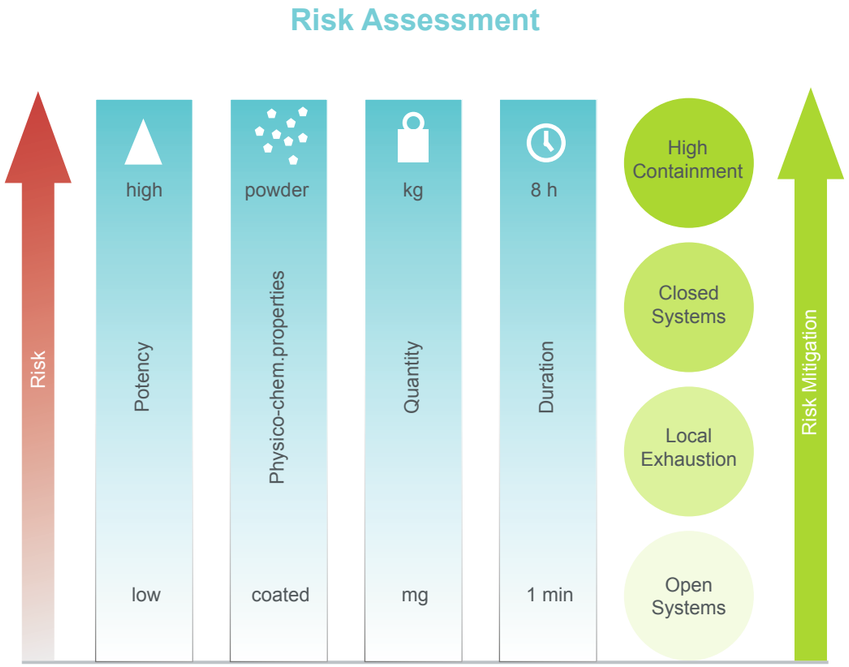


Figure 5 Risk Assessment per process step (Graphic: Aenova Group)

Concentration of the API in the mixture

The higher the dilution of the active substance in the excipient or excipient mixture, the more the potency of the corresponding intermediate is lowered. The degree of dedication and containmet can be adjusted accordingly.

Physico-chemical characteristics of the API

The physicochemical properties of a substance have a particularly large impact on its hazard potential. In case of solid production, for example, a micronized active substance poses a significantly higher risk than a crystalline active substance.

Quantity handled during the process

The handling of larger quantities of active substances, e.g. during weighing, results in a higher risk of cross-contamination. Therefore, this requires a highly contained process, which might be different in case of handling with smaller quantities, e.g., such as sampling.

Duration of the process

The time period of the process is also associated with the risk of cross-contamination and must be considered in the containment concept.

Figure 5 on the risk analysis concept also shows that high- and closed-containment is not necessary in all cases of HPAPI handling. In the case of tablet production, the degree of containment can be reduced as the process progresses. For example, at the stage of coated tablets local dust extraction or rooms with high air exchange rates may suffice.

Closed containment for HPAPI handling, a case study

The following example from the Aenova Münster site shows the structure of an efficient production concept together with a clear material flow.

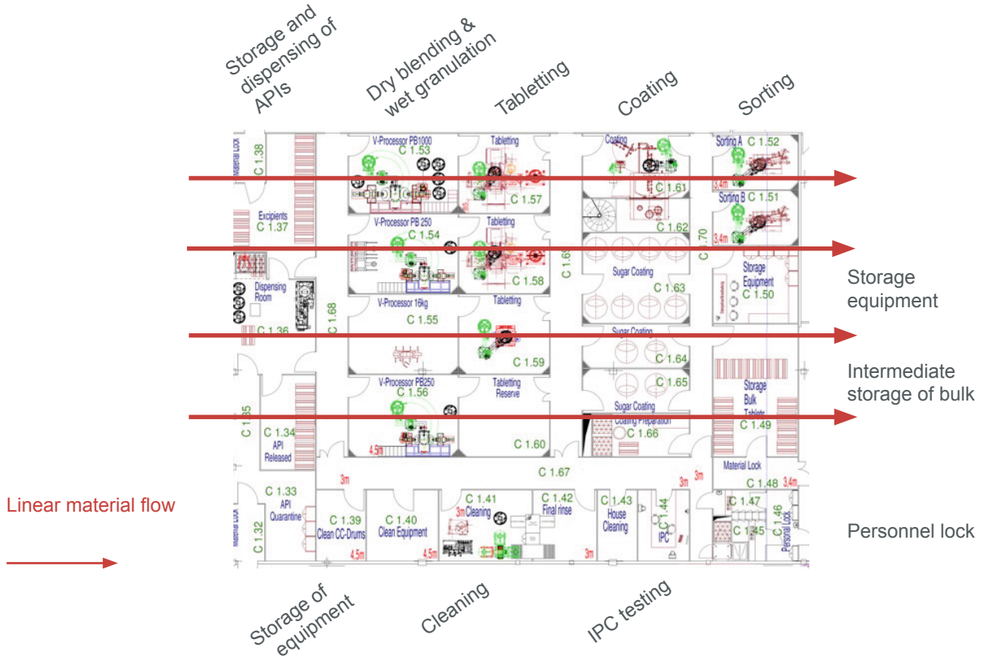


Figure 6 Schematic layout of the closed containment production area for highly potent tablets at the Aenova Group's Münster site

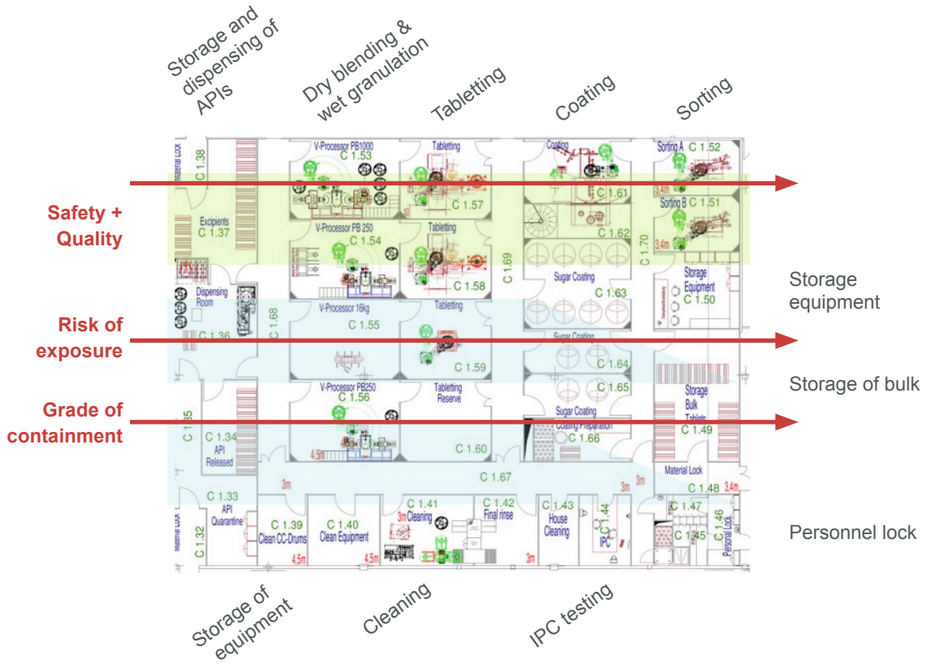


Figure 7 Grade of containment related to the risk of cross contamination

Starting with API dispensing in an isolator all process steps, i.e. blending, granulation, sieving, tableting and tablet coating are executed in a closed containment environment. This equipment train ensures safe and efficient handling of HP products from powder handling to finished dosage form:

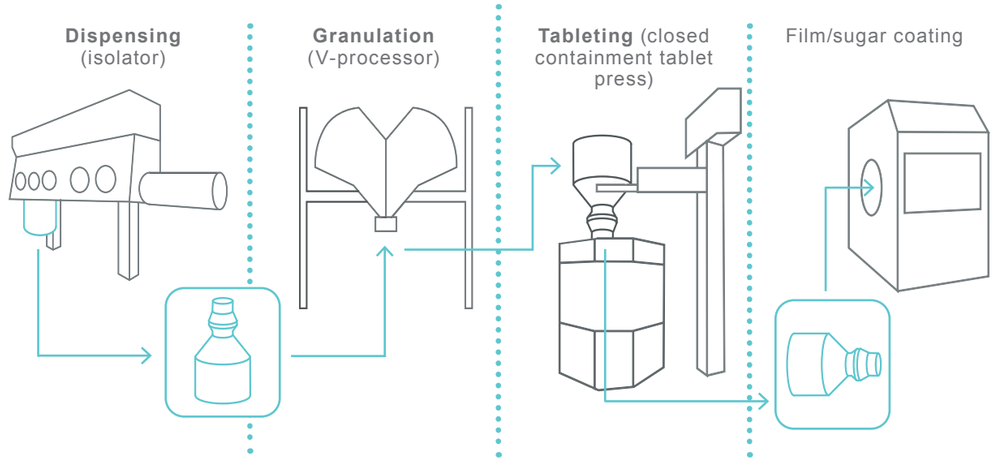
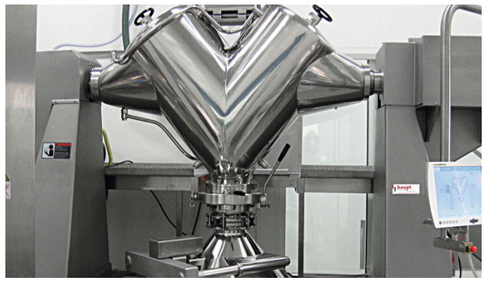


Figure 8 Practical implementation of the Closed-Containment-Concept with real sight on the equipment at the Aenova Münster site (below a-d)

a HPAPI I Dispensing isolator



b HPAPI I V-processor

c HPAPI I Closed containment tabletting

d HPAPI I Film-/sugar coating

a API dispensing in a **high containment isolator** and transfer of the active ingredient into a **closed containment drum**, equipped with a split butterfly valve.

b **V-Processor as a one-pot system** for dry blending, wetting, cutting, drying and cooling of granules without intervention of the process or opening of the processor.

c For compression a **high containment tablet press** is used. The compression module containing the punch set is a closed system with under pressure inside, so that neither the tablet press nor the production cabinet is contaminated by any dust from the product.

d In the final production step, the tablet cores are coated via a **film- and sugar coater** capable for batch of 100-400 kg initial weight. Coating and cleaning programs run fully automated.

The way of closed material transfer is shown as an example of loading and de-loading of the V-Processor.

Figure 9 Loading and de-loading of material

3 Processes

In terms of optimal use of rooms and facilities, workflows and handling, the concept should give priority on safety, quality and reliability, but should also consider a deep understanding of efficiency and optimal use of all resources.

This includes:

- **Lean processes**

  They run through without significant interruption. Intermediate products, such as granulates, are not stored temporarily but processed directly. With careful planning, costs and quality problems associated with hold times of intermediate products can be avoided in this way.

- **Scalable processes**

  They allow the processing of different batch sizes. For example, volume growth of a product can be efficiently supported by adjusting the batch size. This is primarily achieved by considering processors identical in design for different batch sizes, thus enabling an upscaling within factor <10.

- **User-friendly processes**

  The inclusion of production employees in the development of the entire process chain is an essential prerequisite for ensuring that all process steps are user-friendly and found a high level of acceptance among staff.

- **Supporting processes**

  In addition to the main production process, set-up and cleaning processes are also planned precisely. On the one hand, to exclude cross-contamination and, on the other hand, to keep the processes lean and efficient.

- **Room concept**

  The department is divided into many separate production cabinets, each containing only one piece of equipment and operated according to the „one room - one product“ concept. The rooms are supplied separately with HEPA-filtered fresh air via the air conditioning system. In this way, batches of different products can be produced simultaneously in the department.

- **Pressure concept**

  As shown below, the entire department is operated with a sophisticated pressure cascade concept. Clean corridors with automatically interlocked doors have been established to provide additional protection against cross-contamination via airborne particles.

Comprehensive pressure concept in production area dedicated for hormones

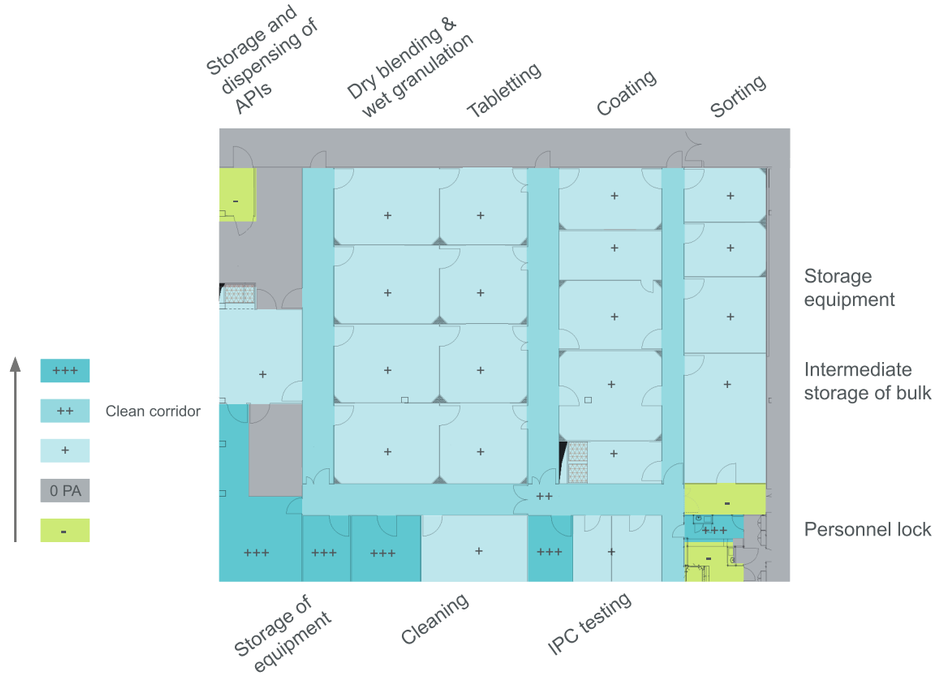


Figure 10 Efficient pressure concept in production area for high potent APIs at Aenova site in Münster (Graphic: Aenova Group)

4 People

In addition to state-of-the-art equipment and well-designed processes, the intelligent production concept rests on a third, particularly important pillar: Highly qualified, experienced and well-trained employees with the appropriate awareness for handling highly potent active substances.

Overall, a very broad, department-overspanning, in-house know-how is required to ensure the safe and efficient development and production of high potent medicinal products. Consequently, it must encompass many other areas besides the actual production process:

Quality assurance

- Experts for in-depth and constantly updated knowledge of the relevant regulations. These must be incorporated into the local SOPs in order to keep the staff up to date via training.
- Experts for cleaning validation

Safety

- Risk management in collaboration with occupational toxicologists, especially in case of introduction of new APIs (OEL and PDE determination)
- Experienced HP product development and tech transfer staff with proven scientists and engineers
- Well-trained team to run a modern HSES concept (Health, Safety, Environment, Security)
- A strong safety culture in terms of occupational hygiene

Production

- Understanding of equipment handling practices and production processes
- Continuity of teams from development to commercial production
- Regular exchange of experience between staff
- Awareness of staff in dealing with HPAPI (all departments incl. cleaning staff)

Quality control

- The laboratory onsite must be capable in trace analysis
- Development and quality control must employ specialists for method development and validation

As a rule, an experienced and reliable CMDO to manufacture HP products must be able to provide these resources or build them up in cooperation with the customer on product-specific basis.

In that way, a long-lasting business relationship can grow and customers and ultimately patients significantly benefit from CDMO's wealth of experience in HP product handling.

3 SUMMARY

1 To ensure safe and efficient handling of high potent products it is key to master a holistic production concept as a basis for the three pillars production equipment, processes and people.

2 Closed containment solutions as an element of an efficient production equipment enable safe and efficient HP product handling.

3 Lean and scalable processes drive resource efficiency, flexibility and scalability.

4 The appropriate HPAPI mindset and culture in all people and the continuity of teams ensure maximum safety and quality from development to commercial production.

5 A CDMO specialized on HP product handling offers competitive advantages paired with decades of experience and expert know-how immediately available.

4 PARTNERING WITH A SPECIALIZED CDMO

Especially for development and manufacturing of high potent products pharma companies world-wide use specialized service providers. According to the concepts and requirements described in this whitepaper, the advantages are obvious:

Experience, know-how, availability

The above described ensemble of production equipment, processes and people are immediately available. Additionally, partnering with Aenova, makes decades of HPAPI experience available. Additionally, customers get access to world-wide market supply based on an extensive inspection track record.

One-stop shop throughout the product life-cycle

Services are overpanning all phases form early development and clinicals trial supply to launch management and commerical manufacturing. The one stop shop approach ensures: fast time-to-market, low project risk and ultimately cost competitiveness.

Scalability

Having 'critical mass' a leading CDMO offers the advantage to provide immediately available capacity at any time. Additionally, choosing a specialized partner offers the potential to grow with the market demands, which is of paramount significance in the fast growing and agile market of HP products.

One-Stop Shop of Choice for HPAPI Products

Four specialized sites for HPAPI handling within the Aenova network

Münster
(Solid dosage forms)

Hormone, hormone-like and low-dosed API drug products

Regensburg
(Solid dosage forms)

Oncology and immuno-suppressant drug products

Wolfratshausen
(Sterile injectables)

Sterile injectables, chemical and biologics drug substances

Kirchberg
(Softgel capsules)

Pharma soft gelatin capsules also for high-potent APIs

With four centers of excellence for HPAPI handling, Aenova is the one-stop shop for the entire product life cycle from development to commercial deployment. In addition to our experts, our most important assets are our state-of-the-art facilities and highly competitive lean manufacturing concepts. We can offer highly flexible technology solutions that are fully scalable from pilot to commercial scale.

"Customers and patients first" is the core value of Aenova. We offer quality, delivery reliability and added value throughout the entire life cycle. In short: "Excellence beyond Manufacturing".

Jan Kengelbach, CEO Aenova Group

About the Aenova Group

The Aenova Group is a leading global contract manufacturer and development services provider for the pharmaceutical and healthcare industry. Our services include end-to-end manufacturing and development of all dosage forms and potency levels (ranging from nutraceuticals to high-potents) out of 15 production sites in Europe and the US.

With our comprehensive know-how, many years of experience, well-trained staff of around 4.200, innovative technologies and highest quality standards we are a reliable, long-term partner to pharmaceutical and consumer health care customers around the world, both in the human and veterinary healthcare market.

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5 REFERENCES

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3 Graphic adapted from NIOSH https://wwwn.cdc.gov/Niosh-oeb/

4 https://www.ephmra.org/sites/default/files/2022-01/2022%20ATC%20Guidelines.pdf

5 CANCERTOMORROW, International Agency for Research on Cancer (IARC, WHO), https://gco.iarc.fr/tomorrow/en/dataviz/isotype?sexes=0&single_unit=500000, website visited 7th July 2022

6 IQVIA MIDAS 2019-2021, High Potent market definition by Aenova (solid HPAPIs of ATC: L1, L2, L4X, G3)

7 IQVIA MIDAS 2019-2021, High Potent market definition by Aenova (solid HPAPIs of ATC: L1, L2, L4X, G3)

8 IQVIA MIDAS 2019-2021, High Potent market definition by Aenova (solid HPAPIs of ATC: L1, L2, L4X, G3)

9 PriceWaterhouseCoopers 2022 Global CDMO Study of Pharmaceutical Operations https://www.strategyand.pwc.com/de/en/industries/health/2022-global-cdmo-study.html

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For 16 years Mrs. Schanz has been working for the pharmaceutical industry as Market Intelligence Manager, Growth Analyst and Market Research & Forecasting Manager. Since the end of 2020, she has been applying her deep and broad knowledge of the pharmaceutical market to Aenova, combined with industry knowledge of large pharmaceutical companies and SMEs.

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