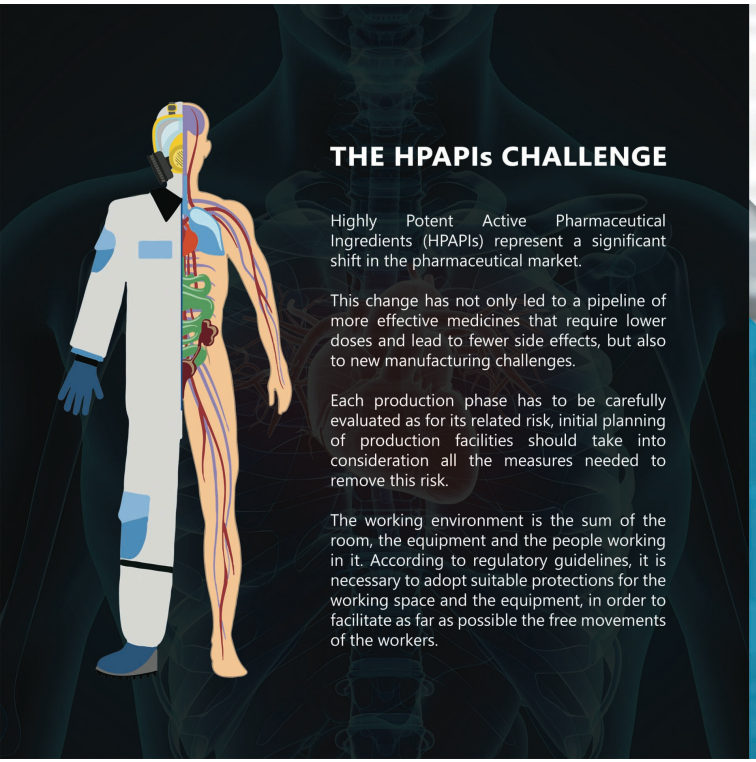

THE HPAPIs CHALLENGE

Highly Potent Active Pharmaceutical Ingredients (HPAPIs) represent a significant shift in the pharmaceutical market.

This change has not only led to a pipeline of more effective medicines that require lower doses and lead to fewer side effects, but also to new manufacturing challenges.

Each production phase has to be carefully evaluated as for its related risk, initial planning of production facilities should take into consideration all the measures needed to remove this risk.

The working environment is the sum of the room, the equipment and the people working in it. According to regulatory guidelines, it is necessary to adopt suitable protections for the working space and the equipment, in order to facilitate as far as possible the free movements of the workers.

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PREVENTING OCCUPATIONAL EXPOSURE TO HPAPIS

CSV Life Science

PolyCrystalLine
experts in crystal forms

CONTAINMENT PERFORMANCE

Standardized Measurement of Particulate Airborne Concentration (ISPE SMEPAC)

ISPE SMEPAC

Containment validation is a critical component of any potent compound safety program.

We offer containment performance testing of any containment system according to ISPE SMEPAC guideline.

The assessment and the consequent test can be applied to new equipment during FAT and/or SAT to confirm the design CPT (Containment Performance Target) or to running system for routine monitoring of the Occupational Exposure level.

APPLICATIONS

- Evaluate containment performance without potential exposures to potent APIs
- Evaluate equipment/devices before purchase
- Obtain baseline data to compare equipment models from different suppliers
- Obtain baseline data to compare different technologies
- Evaluate performance of new equipment before production

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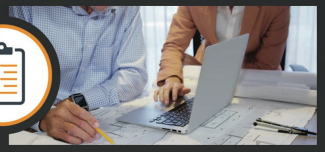
www.csv-ls.com

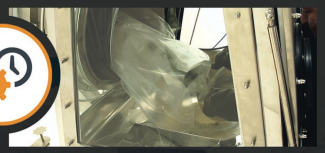
Step 1. SAMPLING STRATEGY AND PROTOCOL WRITING

We will develop an efficient sampling strategy (i.e. type of sampling, where to sample, number of samples, duration of each sample).



Step 2. REPRODUCTION OF ALL PROCESS STEPS

Our operators will reproduce all process steps, unit operations, and tasks.



Step 4. ON SITE SAMPLING

We will perfrom a comprehensive monitoring of air borne and surface samples, accordingly to the sampling strategy developed.

Step 5. SAMPLE ANALYSIS AND VAIDATION

We will perform on the collected samples all required analysis providing a final report with raw data and results interpretation.

METHODS AND SURROGATES

Our method uses a grouping of different samples placed within the air space surrounding the containment enclosure, plus samples located at potential breach points, the worker, the test enclosure, and the air inside and outside the test environment.

We developed highly sensitive and specific analytic methods to monitor the following surrogates: Lactoes, Naproxene and Mannitole.

All our methods are validated according to ICH Q2 R1.

LACTOSE	NAPROXENE	MANNITOLE
• HPLC-ED • CPT/OEL* > 100 ng/m3	• HPLC-UV • CPT/OEL* > 10 ng/m3	• LC-ESI-MS • CPT/OEL* > 10 ng/m3
• LC-ESI-MS • CPT/OEL* > 10 ng/m3	• HPLC-FLUORESCENCE • CPT/OEL* > 1 ng/m3	

* The applicability limit depends on sampling method strategy, the value reported represents the best achievable performance.

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