

## ANNEX 1 PLANNING & CONSULTING

ValSource can help you with an Annex 1 action plan.

An<sup>1</sup>

Know the Requirements

The revision to Annex 1 is detailed — more than 50 pages. ValSource consultants are highly recognized for their Annex 1 knowledge and expertise. We provide a plan forward through Annex 1 updates, today and into the future.

## WHY VALSOURCE FOR ANNEX 1?

We understand Annex 1 and know the requirements.

You need an action plan for Annex 1 — ValSource experts are the most qualified to help with proactive planning and consulting.



### Microbiology & mycology

ValSource has university-trained, industry/FDA experienced microbiologists and mycologists who can offer practical advice and solutions.



### Pharmaceutical quality systems

A PQS with effective elements including change management, training, qualification/validation, and risk management must support your Annex 1 contamination control strategy.



### Quality risk management

Annex 1 requires your Contamination Control Strategy document to include risk assessments and risk-based rationales.



## Manufacturing science & technology

Product life cycle thinking starts at the outset of process/product development. ValSource has experts in advanced therapeutic medicinal products (ATMPs), cell-and-gene therapies, vaccines, and small and large molecule drug products.



## Airflow visualization & interpretation

Annex 1 requires visual demonstrations concerning airflow in critical zones. ValSource has the people, equipment, and skills to create and then interpret airflow or “smoke” studies.



## Aseptic processing simulations

Successful media fills are one of the contributors to having confidence that your aseptic operations are working and under control. ValSource experts have designed risk-based tools to help design and execute meaningful APSs.



## Commissioning, qualification & validation

ValSource has more than 350 technicians and engineers throughout North America who can support your capital projects in a timely, cost-effective way, from equipment acquisition to protocol design to successful completion.





### Training & performance support

What to do and the reasons behind the requirements and practices. ValSource expert trainers can share their experience and knowledge, helping your personnel achieve consistent, practical performance.



### Environmental monitoring strategy

Where should you sample? How many samples should be taken? When and for how long? ValSource consultants can help you create or improve your EM program using risk-based methods that help you get maximum value from each sample.

# ANNEX 1 — AND BEYOND

Together — we help clients manage and deliver compliant-ready, safe projects and products. EPREX, our equipment and service procurement partner provides a single contract and preferred pricing. PIMSHQ, our software solution partner enables on-location, real-time project management.

Our integrated approach is unlike any other in the industry — providing an end-to-end, total project delivery solution to our clients.



# VALSOURCE

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