

*What action do you need
to take to protect your
aseptic operations?*

Lachman
CONSULTANTS
(IRELAND)



Experience. Excellence.™

NAVIGATE THE ANNEX 1 MAZE WITH LACHMAN CONSULTANTS



**You need Experience
and Excellence to
guide you!**

Experience excellence using our experts to assess gaps in Annex 1 requirements and achieve your regulatory compliance goals.



CONTACT US TODAY

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lachmanconsultants.ie

ARE YOU READY?

**Lachman
CONSULTANTS
(IRELAND)**



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Do you have an action plan in place to meet the new regulations by August 2023?

A SAMPLE OF NEW EXPECTATIONS IN ANNEX 1 BELOW.

- Alignment with a holistic look at Pharmaceutical Quality System (PQS)
- Wider view of a Contamination Control Strategy (CCS)
- Review of specific technology (i.e. RABS)
- Integration with Quality Risk Management
- Increased focus on use and management of third parties (component suppliers and critical service providers)

Annex 1 presents a myriad of challenges. We have developed unique methodologies to help companies see their vulnerabilities and assist them in taking the actions necessary to achieve regulatory compliance goals.

Our expert consultants and established techniques are an ideal solution for all of your aseptic product needs, regardless of formulation and active ingredient(s), process or technology.

GREAT COMPLIANCE IS GREAT BUSINESS... LET US HELP.

Start your comprehensive assessment of Annex 1 compliance today.

ADVANTAGES AND BENEFITS:

**Optimum
Regulatory
Compliance**


**Increase
Operational
Efficiencies**

**Reduce Costs
and Process
Complexity**

**Minimise
Compliance
Risks**

**Accelerate
Business
Outcomes**

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