



Aseptic Processing Consulting

In all the pharmaceutical and medical devices companies involved in sterile processes

And, in the Biotechnology scope from development to routine


AXYS-NETWORK

The One – stop – shop reference

About Axys- Network

- Axys-Network is a hands-on oriented pharmaceutical consulting firm, specifically involved with sterile and/or aseptic processing of sterile & injectable drug products
- Axys Network is focusing on sterile drug products to assess risks, improve your performance and troubleshoot process issues. Our world-class experts provide turnkey modules and tools which have already demonstrated their relevance in production sites





About Axys-Network

What do you can expect ?

- Axys-Network can aggregate consultancy and expertise in leading and supporting the senior top-management of your company, the site directors and the projects senior leaders in one – shot mission or on a long-term period.
- So, the facility management of your main preoccupations will be helpful and compliant. Resources on demand and Backoffice as planned and on request ensure to deliver the most efficient service and assistance.
- Axys Network is focusing on achieving your aims for qualitative, technical and scientific answers to the Notify Bodies or to the Legal / regulatory Authorities in a timely manner.

About Axys-Network

Why to work with us ?

- Axys-Network is a worldwide reference to address hot topics, quality issues and critical observations and gaps from external audits and inspections.
- Experts in charge of supporting your company assess the scope of your request briefly with strong accuracy and in-depth reviews.
- Axys Network knows the huge impacts of non-compliance gaps and non-completed remediation tasks and plans. With Axys Network, no loss of time, no oversight of critical topics, no risk of misunderstanding versus the expected rules and state of art. We used to work in such environment for a long time.



Our Experts

Who are they ?

- All the consultants are hands-on experts in their area of competencies and have extensive experience in the industry. They intervene directly on sites, using their know-how to implement the expertise of our network. To ensure the efficiency and effectiveness of our interventions, we offer consulting services that have already been implemented on production sites and have demonstrated their relevance in a pharmaceutical plant
- The scope of our experts cover a wide range of competencies: QP, Microbiologists, Sterility Assurance, Risk management, HVAC, aseptic practices, validation, pharmaceutical waters & pure utilities...Over 200 experts from Europe and the US and the Canada.



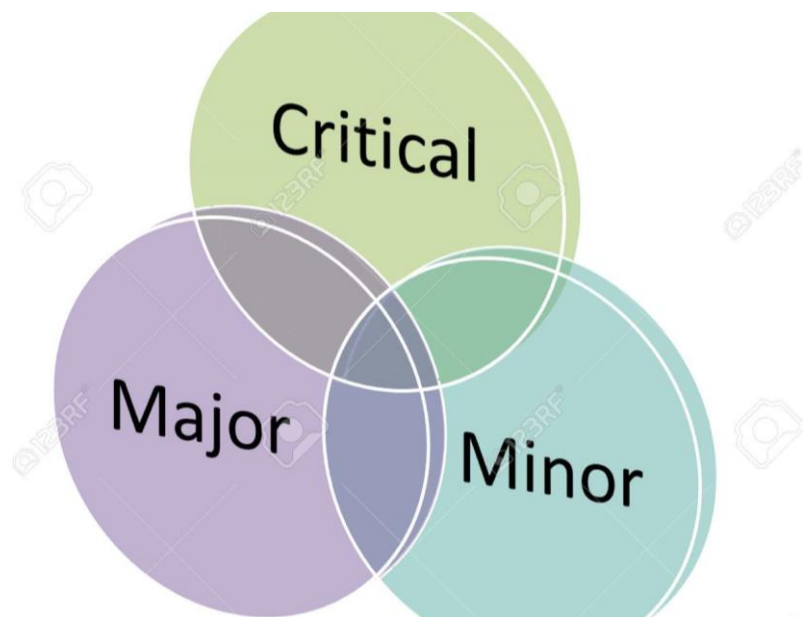


Our Experts

Where do they come from ?

- They spent time (decades in all cases) in high positions in the health care industries as Site directors, QA and QC leaders, Heads of manufacturing, Heads of Engineering, Regulatory Experts at Corporate and Global supports, as Operational Leaders on the shopfloor.
- They have in hands the tools they practiced as Qualified Persons and Responsible Pharmacists when applicable.
- They were staff members and senior top managers in well-known companies, big pharma's and they worked in different countries.
- Working in English, in French, on request in Spanish, German and Russian languages, you'll find the right person at the right place.

NON-COMPLIANCE



Our Services

At a glance for most serenity

- Implementation, Improvement of your QMS : governance, steering committees, process -mapping
- Troubleshooting on short notice: Contamination (microbial, endotoxins and particles), Biofilms, Critical deviations and OOS
- Answers to 483's and all kind of deficiency & warning letters / notifications (US/ EU..) – Manufacturing & Quality issues
- Support to FDA, EMA and worldwide inspections (ANVISA, SFDA, KFSA, MHRA, ..)
- Specific products: noncompliance risks, Data Integrity Contamination Control Strategy (CCS), Human Error Prevention, Proof of concept and related Risk analysis on product, processes and regulatory submissions, validation strategy
- Biomanufacturing support, use of Single Use Systems
- Support for Engineering of Biopharmaceutical Processes from development to industrial routine



About Axys-Network

The ways of working : to initiate the mission in 3 steps

- **First:** plan a contact in face – to- face or by visioconference to collect your needs, to know your constraints, to understand the scope of the mission, to propose and discuss with you on different scenarios. For Axys Network, attendees are the Business Manager, the Scientific Director and possibly one expert at least.



About Axys-Network

The ways of working : to initiate the mission in 3 steps

- **Secondly:** resume the situation in a brief, confirm the scope and the objectives in a formal tender to share in a one-shot mission, or in mixed expertise and mid – term or long – term support, supply of the CV of the dedicated experts involved in the project (in front office or in back-office). Costs quotation. Possibility to engage a drawer offer to consider usual and unusual facts and data, delays and changes in the “true life”.



About Axys-Network

The ways of working : to initiate the mission in 3 steps

- **Thirdly:** Axys Network plans with you the mission in a definitive agenda and reliable / pragmatic schedule. You approve the tender. We deliver and give to you the most relevant follow –up writing Briefs and reports, minutes and recommendations along the way.
- You've a unique contact to share with us on the current implementation of our common achievements.

To summarise

- Axys-Network is part of your commitment
- We're part of your success
- We support and solve the main issues you meet,
- You find in Axys –Network the most efficient consultancy in critical processes and high regulated rules,
- Axys Network and your company are focusing as defined before on sterile drug products to assess risks, improve your performance and troubleshoot process issues.
- Our world-class experts provide turnkey modules which have already demonstrated their relevance in production sites for a long time.





Contact us and learn about us



e-mail :

contact@axys-network.com



Web site :

www.axys-network.com