FDA COMPLIANCE

FDA U.S. FOOD & DRUG ADMINISTRATION

Whether you are currently in the clinic, ready to submit an NDA or BLA, or already have a product on the American market, our team of experts from the FDA and industry can help you build efficient business processes that ensure sustainability and compliance to today's regulatory environment. Axys can support you in organizing your personnel, data, and know how to maximize the probability of success of the inspection with a minimum of stress.

INSPECTION READINESS. HOW DO WE DO IT?

A five day program to assess the current systems, identify gaps and create an action plan.

- Support for implementing an action plan including KPIs for management oversight
- Build focus groups for sensitive areas, depending on the company's situation (data integrity, maintenance, QC laboratory)
- Regular follow up (up to presence on site) ensuring progress against the plan with fully bilingual experts
- Support from simple oversight or assistance in writing necessary documents/procedures, etc.
- Audits with FDA personnel to understand FDA Quality System approach and particular style of inspection by FDA.
- Identification and coaching of SMEs (Subject Matter Experts) that will present to the inspectors.
- Front and back office organization to ensure rapid and coherent response to inspection questions

WHEN SHOULD YOU START?

If you have previously been inspected and want to see that you are maintaining compliance, every twelve to eighteen months you should consider an audit. If it's your first experience with FDA, you should start at least one year prior to submitting your BLA or NDA.

WHY SHOULD YOU WORK WITH US?

Axys brings a unique portfolio of talents to help you succeed in your FDA inspection.
First we have a pool of FDA inspectors with experience in small molecules, biotech, and blood products. These ex-FDA employees have been inspecting and reviewing documents from applicants like you.
Second, we can bring a level of reactivity with our European staff, all having experience with FDA inspection and fully bilingual. So you will have no hurdle of language to deal with, when trying to translate the American requirements into practical documents/procedures/systems.
Third we have a toolbox of diagnostics, checklists, front and back office organization, and KPIs that are really "plug and play". They are ready to go as soon as you are.
Finally, the advantage of being well prepared in the absence of the unknown is a great stress reduction. Yes an inspection is stressful, but when you are properly organized and know the subjects, it's much less so.

WHO ARE WE?

- **John ORSATO**
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U.S. FOOD & DRUG ADMINISTRATION

FDA READINESS

1. POTENTIAL CLIENTS

FIRST EXPERIENCE WITH FDA
You plan on filing an NDA or a BLA with the FDA to gain access to the US market. You have been exchanging with the FDA on clinical trial design and perhaps on some manufacturing issues but are you ready to face your first GMP inspection with the FDA ? Where do you start ?

NEW PRODUCT LAUNCH (PAI or PLI)
FDA has previously inspected your site for an older product, but your recent NDA or BLA has triggered a PAI of a PLI. Things having changes over time, are your quality systems ready for the current inspection ?

ROUTINE PERIODIC INSPECTION
You are expecting a routing GMP inspection, and need assurance that you are not overlooking any issues with your quality systems that you are used to living with and think is OK, but FDA will not accept. An outside opinion is what you need.

2. INSPECTION READINESS

ORGANIZING WITH EXPERIENCED AMERICANS
We can help you understand how the FDA runs inspections according to their internal procedures and their six quality system approach. Identifying your Subject Matter Experts (SMEs) to front each quality system in general, and specific experts identified well prior to the inspection will help insure a more fluid inspection and show that you master the subjects. Using a checklist of over one thousand items, we will make sure you have not overlooked anything.

DIAGNOSTIC PHASE AND REMEDIATION
Prior to thinking about any action plan, we will run a diagnosis on your site and your systems to identify the strong and weak points in your operations. You may need simply some procedures revised due to evolving guidelines, or a more in-depth program.
For example if you need help to reorganize your organization to avoid appearances of conflict, we can advise on that. Or you may have issue requiring time to resolve but you want to continue to operate, and in that case we can help you identify your end goal and the compensatory measure that you can put into place in the interim enabling operations which respect GMPS during the transition.
In addition to organizational and documentation solution, we can bring technical solution (HVAC, water systems, ...) which many GMP consultants cannot bring.
Finally, for the areas which need more concentrated effort (Data Integrity, technical and maintenance conformance are some common points) we can help you set up focus groups to identify your endpoint and the path to transform your operations.

MAKING IT WORK
You have decided to undertake a potentially large transformation program but how to ensure to advance in an orderly manner while tracking progress ? We can show you how to set up the program governance from the operational groups up to the management reporting, including KPIs.

COACHING
Being in compliance and understanding your operations is essential, but not the complete set of cards needed to succeed the inspection. Our couches will help you understand how to answer questions while remaining at ease and very importantly not giving answers that open doors to further questions.
For the inspection to work, you will need a very organized back room to retrieve data and procedures quickly and present them through the identified SME. We will show you the optimal organization.
Finally, some initial presentations on subjects can put inspectors at ease prior to looking at procedures of data. Expert presentations (water systems, HVAC, calibration/maintenance, people and material flow) are necessary and we can help you here.

3. SOMETIMES THINGS GO WRONG

You may have received feedback from the FDA to which you have to respond quickly. In the order of seriousness they are 483 points, a warning letter, and a consent decree. We can help you respond with the proper level of commitment in the time required.

4. NOT IN THE GMPs BUT IMPORTANT

Is your pharmaceutical development or your Quality Management systems up to the standard of the ICH series ? Have your risk analyses identified the CQAs and CPPs that ensure process reproducibility as the FDA currently expects ? Have you optimized your CPV and APR systems not to do the same work twice ?

5. WHY AXYS NETWORK

AXYS has a blend of experts with a wide range of experiences. Our vision is to establish a program with an ex-FDA inspector giving the oversight. And the day to day operational progress is ensured by francophone experts with extensive experience with FDA inspections who can work with you on the ground at the level needed, from mentoring all the way to authoring procedures and training. Our presence in France has no time zone difference or language barrier.
Additionally, some points are difficult without experience, such as the appropriate method of analytical method validation and process validation during clinical development. We can ensure that your GMP compliance moves ahead with your clinical development phases.
Finally communication with the FDA can be intimidating, be it routine exchanges of information or briefing packages for FDA meetings. Our experts have the experience to help you.

***ICH Q 8/9/10**: from product development, initial determination of CQAs & CPPs, validation strategy, control strategy/sampling plans, continuous verification, and management overview of quality systems and quality metrics*
***Quality system evaluations and remediation**: verification of existing systems and remediation where necessary to comply to modern regulatory standards; ensuring the proper level of management oversight*
***Building an effective quality organization**: functions, systems, reporting, staffing, independence*
***Quality documentation system**: structure, coherence, redundance, streamlining/optimizing, creating a match to business processes*
***Data integrity**: mapping and clarification of data ownership, review and modification of practices, conformance to Part 11 and Annex 11*
***FDA readiness**: initial diagnostic audit, quality system checklist (> 1000 points reviewed), identification of SMEs (Subject Matter Experts), coaching for the inspection, front and back office organization, focus groups depending strength/weakness of organization*
***Laboratory compliance**: methods and validation, product and component specifications, stability programs, control of reagents, conforming documentation*
***Technical Services**: often overlooked, calibration and maintenance ensuring equipment fit for use.*
***Personnel** : relevant training for personnel, job descriptions, records and documentation necessary for regulators*
***Risk Management**: identifying and managing risk (facilities, process), attenuation or compensatory measures*
***CTD review**: ensuring the proper level of detail in your regulatory filings*
***Batch release**: are you releasing batches based on the proper information, and are your exceptions closed out prior to the release ?*
***Technical Services**: are you maintenance and calibration systems performing at the proper level with the necessary controls, both technical and quality)*
***Training and personnel records**: be sure that your*
***Regulatory Response**: be it a inspection 483 list, warning letter, consent decree including third party oversight, we can help you through the situation when things don't go as expected.*

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