



FACTSHEET cGMP QUICK SCAN: LICENSE-TO-OPERATE

ARE WE COMPLIANT?

As a senior executive within Life Sciences & Healthcare, you will recognize the potential risk of your organization for not being compliant, putting your license to operate and sell at risk.

You might have experienced a recall of one of your products, and the impact on your business and reputation. Or you might be developing a new drug and seeking guidance to be compliant. Do you recognize these questions?

- ▶ *Are we compliant? Are we overcontrolling and having too strict internal guidelines?*
- ▶ *How to best allocate our resources? Are we overspending or underspending? How to monitor the outcome of our investment?*
- ▶ *Do we have the right expertise internally?*
- ▶ *Are we putting our license to operate at risk?*

WHAT CAN WE DO FOR YOU?

Our Progress-EXS experts, who have experienced these challenges themselves, have developed the License to Operate Quick Scan tool (cGMP).

The License to Operate Quick Scan is a risk management tool facilitating the rapid identification and visualization of current and potential cGMP gaps, risks and opportunities for your organization. This tool is a 'temperature' measurement of how far you are from being non-compliant. We can also support you with correcting identified gaps and setting up a robust strategy, to secure your license to operate.

Besides, we seek for opportunities to improve the best use of your limited resources.

Evaluating your compliance and quality system strategy with fresh eyes to assess that your license to operate is not at risk.

WHAT CAN YOU EXPECT ?

At the end of the License to Operate Quick Scan you should have a good understanding of current and potential gaps linked to your compliance system, a better understanding of the risks these gaps imply, and a good comprehension of what is being expected from authorities, considering current industry standards. A detailed report, including all findings rated according to criticality, will be provided; as well as a presentation at executive level summarizing findings, explaining the status, giving recommendations and defining a mitigation plan.

We understand your challenges and we want to facilitate your effective decision-making process to secure your license to operate and sell.

HOW TO PROCEED?

If you hire our services, the first step is to meet and to understand your specific needs. We expect a senior manager or executive explaining what your challenge is. This person will act as our sponsor at your organization. The next following steps will be:

- ▶ Kick off meeting (1 day)
- ▶ Technical visit (1-2 days)
- ▶ Data analysis and reporting (1-2 weeks)
- ▶ Executive presentation (1 day)
- ▶ Mitigation plan execution (upon request)

We believe that every company and every situation require a tailor-made approach. This is the reason why we strive for an open communication and transparent interaction to best understand your needs and provide you the support you need.



TYPICAL cGMP PITFALLS

Current Good Manufacturing Practices (cGMP) are embedded in all the activities your company executes. Staying compliant is a clear requirement from all regulatory bodies and the risk of having a recall, a major observation or even a warning letter, may have a permanent damage on your business and your company reputation. Some related cGMP pitfalls frequently encountered are:

- ▶ Spending too much money and not yet being compliant: ineffective implementation of Quality Management Systems

- ▶ Corporate governance: Senior QA management not able to influence company operations
- ▶ Knowledge gaps and lack of understanding on what is required to stay compliant
- ▶ Lack of clear and robust monitoring process: securing that the implemented system stays compliant according to changing regulations
- ▶ Data management system not in place or not well established. Resulting in an insufficient and highly inefficient process data traceability
- ▶ Departments working in silos: lack of common understanding