38-Point Lean Compliance Self-Assessment

Use Cerulean's 38-question self-assessment to help you begin to identify costly gaps in your organization's quality systems program.

Cerulean provides lean compliance onsite workshops and online seminars, plus independent mock FDA diagnostic audits with detailed, prioritized recommendations and suggested remediations. Clients can then use Cerulean's report to close these gaps themselves or draw upon the report to issue a request for proposal (RFP) to bring in outside help. For more information, please contact us today through the Cerulean website (www.Ceruleanllc.com).

Instructions

Answer each question below to the best of your knowledge. If you are not sure or do not know, chances are you should mark "No." Do not mark "Yes" unless you have some level of documented proof (*e.g.*, training schedules, audit report in hand, etc.). **This is the time to be critically honest**.

There are 38 questions. At the end of the self-assessment is a rating scale.

#	Lean Compliance Question	Response
1.	Do you regularly communicate (through meeting updates, status reports, memos, etc.) quality systems continual improvement achievements both up and down the organization?	Yes No
2.	Have you identified subject matter experts (internal or external to your organization) for each quality systems component (*e.g.*, risk management, FDA's Part 11 or EMA's revised Annex 11, quality by design, supplier oversight, etc.)?	Yes No
3.	Are process flows in any standard operating procedure (SOP) mapped (*e.g.*, flow diagrammed) with key decision points identified?	Yes No
4.	Are visual clues in place to communicate quality standards (*e.g.*, poster with photographs of acceptable versus unacceptable product, poster of your quality policy, etc.)?	Yes No
5.	Are your SOPs and policies based on a common format or template?	Yes No
6.	Are your SOPs and policies written for readability and usability (*e.g.*, score, ideally, between 11-14 on the Flesch-Kincaid Grade Level)?	Yes No
7.	Do your SOPs demonstrate coordination between operational groups and workflows to ensure process handoffs are controlled?	Yes No
8.	Do you restrict SOP- and form-required signatures for approval to three or less?	Yes No
9.	Have you identified the cycle time for an SOP (from conception through approval, training and implementation)?	Yes No
10.	Have you used color-coding (or other visual distinction) in your SOPs and process diagrams to enable easier point-of-use review (*e.g.*, specific Quality Unit actions in an SOP are in green, specific Engineering actions in the same SOP are in blue, etc.)?	Yes No
11.	Is a cross-functional team used to walk through any drafted SOP to identify gaps, bottlenecks, duplications, or inefficiencies?	Yes No
12.	Are all acronyms in your SOPs and policies defined the first time they are used in the document?	Yes No

#	Lean Compliance Question	Response
13.	Are personnel training records regularly reviewed by functional supervisors for gaps and refresher needs?	Yes No
14.	Have managers and supervisors been provided “train-the-trainer” experience (or the equivalent)?	Yes No
15.	Do you regularly audit your offices and facility locations for old SOPs and policies still in circulation (or otherwise retained by personnel)?	Yes No
16.	Do you use a documented risk-based prioritization schema to plan new or revised SOP and policy activities?	Yes No
17.	Does the senior management team take part in your quality systems management review?	Yes No
18.	Is your SOP cycle time (see question #9) reviewed for improvement in your quality system management review?	Yes No
19.	Are workflow diagrams that duplicate current SOPs posted in key production, service or lab areas (*e.g.*, the diagram of steps in handling a complaint is posted for the personnel who handle complaints)?	Yes No
20.	Do your SOPs include simple operational checklists or forms designed to allow self-verification of procedural compliance?	Yes No
21.	Do you tackle the “what’s-in-it-for-me” (WIIFM) syndrome in your SOP and compliance training?	Yes No
22.	Have you identified your average nonconformance (or corrective and preventative action) cycle time (from discovery through investigation and resolution to verification)?	Yes No
23.	Do you audit for compliance and currency any posted work flow diagrams or other visual clues (see question #4)?	Yes No
24.	Have all regulated processes (including record maintenance, quality system management reviews, etc.) been defined in an SOP?	Yes No
25.	Do you hold a quality system management review at least once a year?	Yes No
26.	Does your quality policy include quantitative targets to measure results against?	Yes No
27.	Are these quantitative targets – and their status – regularly communicated up and down the organization?	Yes No
28.	If you are not inspected by the FDA or regulatory agency at least every other year, do you schedule third-party independent mock FDA audits every two years?	Yes No

#	Lean Compliance Question	Response
29.	Are your continuous improvement projects identified in your quality systems management review?	Yes No
30.	Does your quality systems management review identify and document funding for projects in the upcoming budget cycle?	Yes No
31.	Are compliance training sessions (on SOPs, policies, etc.) periodically reviewed by senior management for effectiveness and productivity?	Yes No
32.	Would it be easy for a stranger (such as an FDA investigator) to visit your facility and identify product (or paperwork) workflow?	Yes No
33.	Do your internal quality systems audits include reviews for duplicate or outdated activities, controls, or other non-value processes?	Yes No
34.	Is a clear and measurable action plan in place for each nonconformance or corrective and preventative action?	Yes No
35.	Does an overall cross-functional training matrix exist showing the level of training for each person?	Yes No
36.	Are all functional managers and supervisors trained in risk-based decision-making and tools (*e.g.*, HAACP, FMEA, etc.)?	Yes No
37.	Is senior management comfortable with current FDA rules, ICH and/or GHTF guidelines?	Yes No
38.	Does management regularly adapt business initiatives and funding to incorporate new FDA regulatory intelligence and quality systems expectations?	Yes No

Scoring

Count the total number of questions that you answered "No" and compare to the chart below.

Note: if you outsource a majority (or all) of your company's quality systems work to other companies or independent contractors, multiply your total "No" count by 1.15. If you are not fluent in the language spoken by your outsourced providers, multiply your total "No" count by 1.45.

# of NO's	Consequences
36 or more	***Fiasco.*** Do the phrases "*fiscally irresponsible*" and "*failure to establish an effective quality system*" ring any bells?
27-35	***Critical risk.*** Your FDA quality system is full of wasted efforts, lost monies, inefficiencies, and non-compliance. Get help now.
13-26	***High risk.*** This is the range of most companies who see low rates of return while receiving FDA 483 observations and warning letters (not to mention the increasingly prevalent disgruntled shareholder or whistleblower lawsuit). Without significant improvement, you should not expect to pass an FDA, EMA, or other third-party audit (such as ISO), nor be able to adjust to increasing cost scrutiny from healthcare reimbursement agencies (such as CMS in the US or the UK's NICE).
4-12	***Low-Moderate risk.*** Good work. Use the questions in this self-assessment to guide your future improvements. Consider bringing in an outside expert to conduct a workshop tailored to your needs to help define and jumpstart reasonable improvements.
3 or less	***Congratulations!*** You are on your way to best-in-class lean compliance. Consider scheduling a mock FDA audit and diagnostic every two years for an independent review and identification of potential opportunities for improvement.