

„The Pharmaceutical Industry – Quality Health Check 2014“

Fragebogen von NSF Health Sciences

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Do you want more of the same or something different?

If you want to improve you have to do something different.

As one year closes and another one beckons it's a time for reflection, looking back as well as forward. How did you do in 2013, and what does 2014 and beyond look like? For many, 2013 has been a real rollercoaster on the business and compliance front. Some of the more sceptical industry observers would say there have been more lows than highs:

- Continuing **increase** of Warning Letters, Consent Decrees, Field Alerts and Recalls
- Increasing **price regulation** as governments attempt to balance healthcare budgets
- **Supply chains** of bewildering complexity... and associated risk
- The unrelenting drive to **cut costs**
- Problems with **data integrity** as some companies ignore their moral compass (thankfully, only a very small minority, but we are all at risk of being painted with the same brush)
- Increasing levels of **counterfeits and falsified medicines** as criminals attempt to cash in, no matter what the consequences
- The **erosion of expertise** as those with the knowledge of what works and what doesn't leave, taking with them thousands of combined years of knowledge and wisdom
- **More regulations** to understand, interpret and embed... only with fewer or less experienced staff to implement them
- The need to **reengineer quality systems** built for a bygone era
- **Regulators struggling** with their own challenges and smaller budgets as they try their best to protect us all from unsafe medicines and poor GMP standards

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In an unpredictable world, one thing can be guaranteed... that nothing can be guaranteed. We are privileged to work with some of the best companies in the world. We have found that **best-in-class organizations** ... have a few things in common:

- They invest heavily in **skills and competencies**. They **educate, not train**
- They demonstrate **excellent leadership and teamwork**. One team, one purpose, guided by a moral compass that keeps everyone on track, no matter what
- When mistakes are made, they **learn** from them, **not repeat** them
- They focus on doing the basics (core competencies) very well and **keep things simple**. They don't try to do everything and work hard to **drive out complexity and ambiguity**
- Although they know what they are good at, they also know where they must **improve**
- They implement **improvements with precision and discipline**. In these organizations, actions speak louder than words

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Your free 2014 “health check” is your opportunity to get everything in order. To be prepared for success, all you have to do is:

- Complete this really simple health check **questionnaire**. It will take only 10-15 minutes, but covers each key element of your quality management system
- **Publicize it widely.** Take it to your next team meeting. Leave copies in your coffee room. Circulate it on your intranet. Put it on your notice board. Ask as many people to complete it as possible. In our experience, you and your colleagues already know your strengths and weaknesses; you just didn’t have an opportunity to share them. Until now that is!
 - **Just answer each question with a yes or no**
 - **Any no’s should act as a catalyst for action!**

So, circulate the questionnaire widely, discuss openly, mark yourself honestly and act diligently.

QMS Health Check 2014

Questionnaire

- **Policies and Procedures:** Do they make your life easier and add value?
- **Education:** Do you focus on changing behaviors, not just checking the compliance box?
- **Quality Risk Management:** Is QRM integrated, value-adding and part of your company DNA?
- **Deviation and CAPA:** Are “mistakes” catalysts for improvement? Considered good, not bad?
- **Quality Metrics and KPIs:** Do they drive the right behavior toward improvement, not punishment?
- **Internal Audits and Self-Inspections:** Are you really inspecting?
- **Change Control:** Does your system manage risk, prioritize resources and drive improvement?
- **Validation:** Do you REALLY understand your processes or just check the compliance box?
- **Data Integrity:** Is it considered to be your life blood, or just assumed?
- **Your Quality Culture:** What do people do when no-one is looking?

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Let's focus on doing the basics well

- Fragebogen online: www.nsf.org oder www.austria-qp.at
- **Next steps:** Scoring (only 10 – 15 min)
- Write down the areas where you scored “No”
- Are these areas featured in your 2014 Goals and Action Plan?
- Write down ... what do you need to tackle these concerns in 2014?