AGING FACILITIES

by Nicholas Markel

Aging facilities is a trendy catchphrase that has taken hold in the biopharmaceutical industry the past few years. While most of us understand intuitively what the words mean, it might be more difficult to identify if age has indeed caught up to your facility and if so, what, if anything, can be done about it.

Let's face it, age is a universal fact that happens to everyone and everything. You may be one of the privileged few that started in the industry 25+ years ago and have been lucky enough to design, build, commission, qualify and operate new state-of-the-art facilities. It might be painful for you to realize that all of a sudden your baby may now officially be considered an aging facility. While we all recognize that aging is natural, we may not always accept that our beloved baby has aged. Just like people, as facilities age they likely need a bit more maintenance than they did when they were young.

AGE IS ONLY A NUMBER

Just because your facility is old doesn't necessarily mean it's aging and furthermore, to date, no regulatory inspection report has cited aging facility as an issue. So, how can you tell if you have an aging facility? This question is often answered by indirect indicators. Ask yourself some of these questions and if the answers are overwhelmingly yes, then you may have issues which need to be addressed.

- Do clients, customers or regulators inquire about your capital improvement plans?
- Is attention being paid to maintenance metrics like breakdown rates?
- Are your flows atypical? For example, do personnel, materials and waste enter and exit through the same airlock and you find yourself implementing temporal solutions?

- Do you find "glitter" when wiping your stainless-steel finishes with a finger or paper towel?
- Do your process demands outstrip your water supply?
- Do you find yourself turning to places like eBay to keep your equipment running?
- Does your automation not have audit trail functionality?
- Do you find yourself having to decrease the amount of time between events like preventive maintenance and requalification?
- Does your budget for equipment maintenance and spare parts increase year after year?

GREAT! MY FACILITY IS AGING. NOW WHAT?

The industry as a whole is struggling with this question. Potential solutions can run the gamut from getting evermore creative with procedures to address engineering deficiencies, to investing in new equipment, to building new facilities. Each approach has its pros and cons and therefore, the decision on which direction to take is complicated. The decision should consider factors such as process robustness,

▶▶

cost, regulatory hurdles and ongoing compliance. These factors inherently create a dynamic tension between maintaining the status quo vs. improvement and innovation. Many of us have older facilities, running older (well-established) processes, and we find ourselves compensating with creative solutions rather than taking the leap and adopting new technology or innovating. So why is this? Shouldn't innovation be encouraged and supported? Some of the uncertainty seems to be related to the perceived lack of clarity regarding expectations from regulatory authorities. Credit should be given, however, as regulatory authorities seem to be making progress as supported by the recent decision that water for injection made via distillation or reverse osmosis is now considered acceptable by both U.S. and EU regulators.

NEXT STEPS

If after considering the questions above you feel you do have an aging facility and are perhaps suffering from a bit of paralysis by analysis, consider reaching out to us for a conversation. We can help you develop a plan to include both immediate (e.g. document rationale and risk assessment for atypical layouts) and long-term (e.g. strategic plan and discussion with regulators) fixes.

Contact **pharmamail@nsf.org** or **USpharma@nsf.org** in the U.S.

ABOUT THE AUTHOR

Nicholas Markel has 25 years of experience in the biopharmaceutical field and 15 years of experience providing general and strategic consultation to domestic and foreign clients in the biotech, biologic and pharmaceutical industries assisting with manufacturing issues, development of quality systems and regulatory strategies. Mr. Markel's areas of expertise include techniques used in biopharmaceutical production for human use, review and development of quality systems, conducting cGMP compliance audits, deviation investigation, CAPA generation and implementation, oversight of manufacturing contractors and manufacturing activities, overall project management, commissioning of new and revised facilities, process validation, man-in-the-plant services to oversee operations and compliance.

For more information, contact **pharmamail@nsf.org** or visit **www.nsfpharmabiotech.org**

Cite as: NSF International. December 2017. Aging Facilities. NSF: York, UK.

NSF INTERNATIONAL | PHARMA BIOTECH

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999 | **E** pharmamail@nsf.org

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA
T +1 (202) 822 1850 | **E** USpharma@nsf.org

www.nsf.org | **www.nsfpharmabiotech.org**