# BioPhorum disposables five-year plan – half time report

**BioPhorum's disposables five-year plan is approaching the halfway point in 2018. Starting in 2016 and composed of several workstreams, the plan was designed to deliver one overarching vision by April 2021: to enable disposable components, assemblies, and technologies to be utilized with the same confidence currently afforded to stainless steel. 2018 is a pivotal year as the biopharmaceutical manufacturers and disposable technology suppliers work together to implement various best practices and guidelines to enable the benefits of disposable technologies to be fully realized across the industry.**

EKTA MAHAJAN
TECHNICAL REGULATORY PROGRAM DIRECTOR
GENENTECH INC
A MEMBER OF THE ROCHE GROUP

KEN WONG
DEPUTY DIRECTOR OF PROCESS TECHNOLOGY
SANOFI PASTEUR

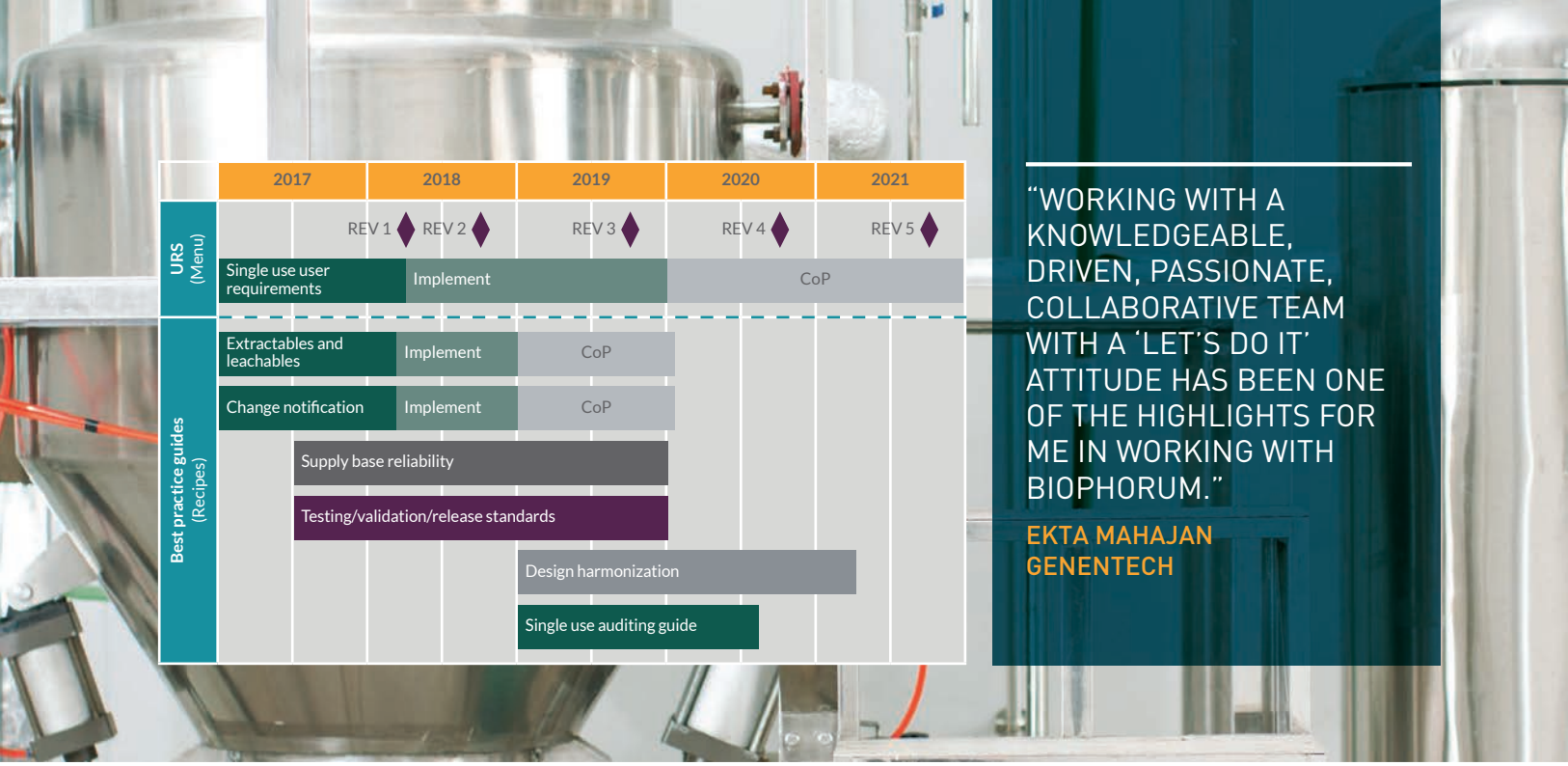
Ekta Mahajan, Technical Regulatory Program Director at Genentech Inc, and Ken Wong, Deputy Director of Process Technology at Sanofi Pasteur, reflected on the milestones achieved by the collaboration in 2017, as well as the next steps on the path to fulfilment of its vision. "There were major advancements in 2017 in BioPhorum's five-year plan for single-use technology (SUT)," said Wong. Mahajan pointed to such milestones as the development of the template for user requirement specifications (URS) for consumables and hardware and the publication of extractables & leachables and change notification best practices guidelines as evidence of the tremendous progress made by the collaboration in the past few years.

BioPhorum and the BioProcess Systems Alliance (BPSA) have collaborated to develop the URS templates and the best practices for change notification for single-use biomanufacturing systems. Published in June 2017, these guidelines aim to facilitate communication and process standardization while improving upon processes related to compliance and continued patient safety.

BioPhorum's best practices guide for evaluating leachables risk from polymeric single-use systems used in biopharmaceutical manufacturing was published in March 2017 and is widely regarded a landmark for advancing increased uptake of SUT, which had been hindered by concerns about the potential risk of extractables and leachables in SUT.

Wong also cited recent publications by BioPhorum's Multi-Product Facility community of practice—particularly, the white papers regarding lean changeover and elastomer change out—while Mahajan noted the receipt of extractable data packages from suppliers that are aligned with BioPhorum's standardized extractables protocol (first published in 2014). "The extractable data package reduces time for qualification of single-use components and URS for single-use equipment, eliminating error," she said.

Each of these achievements is emblematic of the benefits of industry-wide harmonization and collaboration. Said Mahajan, "BioPhorum allows us to leverage experience from other end-users in the industry and helps with benchmarking. The industry is working as a group, with one 'end-user' voice providing consistent messages to all suppliers."




"WORKING WITH A KNOWLEDGEABLE, DRIVEN, PASSIONATE, COLLABORATIVE TEAM WITH A 'LET'S DO IT' ATTITUDE HAS BEEN ONE OF THE HIGHLIGHTS FOR ME IN WORKING WITH BIOPHORUM."

EKTA MAHAJAN
GENENTECH

BioPhorum also enables members to bring value back to their own companies. "I conducted a specific benchmarking survey related to extractables and leachables practices with disposable storage bags," Wong said. "Ultimately, that exercise proved valuable in helping me to gain support from our quality group [at Sanofi Pasteur] and to get buy-in to my proposed changes. To my knowledge, this invaluable information can only be harvested in a timely manner within the BioPhorum consortium—more effectively than with any other venues."

"The value of the BioPhorum collaboration can be measured in several areas," continued Wong. "First, cost. Cost savings are realized by avoiding performing extractables tests on SUT. Second, compliance. We can modernize our processes with clear knowledge that such practices were already in use by other members and with broad acceptance by agencies. Joint members' implementation efforts also help reduce compliance risk with agencies. And finally, efficiency. Once the outputs are adopted by members, efficiencies in cycle and delivery times can be improved and waste from outdated processes can be eliminated."

"Working with a knowledgeable, driven, passionate, collaborative team with a 'Let's do it' attitude has been one of the highlights for me in working with BioPhorum," said Mahajan. "It's a group of passionate, collaborative, hard-working end-users who want to streamline and simplify implementation of SUT in the industry. It is not biased or driven by ulterior motives or conflict of interest; we enjoy open, honest discussions."

"The BioPhorum collaboration is, to my knowledge, one of a kind," said Wong. "It is not only about collaboration like other consortiums. We also focus on implementation and help drive return on investments back to each member. Additionally, the governance process is the most advanced and mature partly due to the volume of workstreams and number of members involved. I have personally witnessed and experienced the evolution of the workstreams, Phorum governances, and decision-making processes over the last five years. The routine workstream/governance face-to-face team meetings have promoted trust among members and sustained the open collaboration and sharing of experience with a shared vision towards our challenges. We find common issues to tackle together for the good of the community and, ultimately, for each member."

While the Disposables collaboration has made great strides, its work is not yet done. In 2018, two additional workstreams will be kicked off—Testing, Validation and Release Standards and Single-Use Performance Robustness, building on the momentum toward realizing its five-year vision. "We want to focus on areas where standardization is needed," said Mahajan. "Any efforts that are difficult as an individual company can benefit from a collaborative industry effort."

"We will continue to allow members to discuss and develop better industry practices where specific requirements are lacking," added Wong. "Our aim is to be the trusted consortium to provide and drive clarity concerning specific challenges associate with SUT in the industry and to influence regulators by harvesting science and knowledge from members."