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NOTE FROM IPQ'S EDITOR-IN-CHIEF: There is a lot of attention being placed now on how to apply the advancing IT toolbox to modernize the way quality information is collected, submitted, processed and managed during the development and application review process. FDA's KASA and related PQ/CMC initiatives, the consortium Accumulus Synergy, and ICH through a revision of M4Q are among the important loci of this effort. Leaders of these four projects met at a session of the FDA/PQRI conference in December to provide an update on their progress to date and goals going forward.

The five parts of the first story in the January/February Monthly Update *(pp. 4-62)* focus on what they had to say regarding: ● the advancing knowledge-aided assessment ("KA") Component of KASA ● bringing biological products into the KASA system ● the progress of FDA's PQ/CMC initiative ● the goals of Accumulus Synergy in CMC data IT and regulatory communication, and ● the drivers for revising ICH M4Q and evolving the CMC regulatory process.

The second story *(pp. 63-95)* explores FDA's effort to strengthen its interface with industry around manufacturing modernization and the use of advanced technologies as key in getting better medicines to patients. Included are a wealth of insights from two champions of this innovation effort, Janet Woodcock and Jeff Baker.

The story begins with a look at Woodcock's transition to a new leadership position at FDA, Principal Deputy Commissioner, and how this will allow her to continue her strong contribution to the effort in the US and around the world to make drug and biologic regulatory processes as supportive as possible of manufacturing innovation. At the last National Institute for Innovation in Manufacturing of Biopharmaceuticals (NIIMBL) annual meeting held in July 2021, Woodcock had an opportunity to reiterate her concern with and commitment to strengthening the industry/regulator interface around manufacturing modernization during a "fireside chat" with NIIMBL Director Kelvin Lee.

A similar review is provided of Jeff Baker's contributions to the advanced technology dialogue during his decade of service as Office of Biotechnology Products (OBP) Deputy Director. Baker had a chance to share the learnings from his engagement with manufacturing modernization at the 2021 PDA Annual Meeting held about a month before he retired from FDA. Like Woodcock, Baker will be continuing his valuable support for the efforts to address the innovation challenges in his new position as a senior fellow for NIIMBL – a position that flowed from his having served as a liaison for the agency with the institute during the latter part of his OBP tenure.

Included in the story are additional insights on the innovation challenges and the agency's efforts to help address them – as well as the adaptations made and novel tools used during the pandemic – provided by Woodcock at FDA's October 2021 Pharmaceutical Quality Symposium and by Baker in a December 2020 "FDA Insights" interview with then Deputy Commissioner Anand Shah.

Receiving IPQ attention is an informative release by Manufacturing USA on how the institutes in its network, including NIIMBL and BioFabUSA/ARMI, are working to fill in the technological gaps in being prepared for health emergencies like the current pandemic. We also review a complementary paper published in 2021 by key industry thought-leaders including Baker laying out in more detail the ambitious biopharma development and manufacturing test bed project NIIMBL began planning before the pandemic emerged.

Of note in our Updates in Brief section for the January/February issue *(pp. 96-103)* in the US are: ● the user fees for prescription drugs, generics, and biosimilars user fees, which are coming up for renewal ● the reports on the past year's activities across CDER and CBER and guidance plans for this year ● guidances on ANDA, combination product, and OTC monograph communications, and ● FDA and USP work in the compounding, mRNA testing, and CBD arenas. In Europe, developments are highlighted involving: ● EMA's 2021 regulatory activity and its recent guidance in the GMP/GDP arena, and ● EDQM/Ph. Eur. offerings regarding CEPs and monographs. Internationally, in focus are guidances from: ● PIC/S on GMPs ● China on drug/device combination products, and ● India on API labeling.

There were 10 FDA drug GMP warning letters posted during January and February *(pp. 104-111)*. These included in the US two to compounders, three to finished dose manufacturers – one of which involved data integrity concerns and one both drug and device GMPs – and one to an HCT/P processor. Internationally, two went to finished dose manufacturers in China and South Korea, and two to API suppliers in India.

Among the 59 drug recalls listed by FDA during the two months *(pp. 113-117)* were eight rated Class I involving products marketed without an approved NDA or ANDA – six dietary supplement capsules products containing tadalafil and/or sildenafil, and two hand sanitizers containing methanol. Also rated Class I were a mislabeled syringe, an injectable with hair, and ointment, syrup and intrauterine products with microbial contamination.