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BUSINESS

Parexel Exec Says FDA Keeps Reviews on Track amid Staff Cuts, but Notes Leadership Drain

By Takashi Ebisawa September 30, 2025

Paul Bridges, President, Consulting, Parexel

The US FDA has largely maintained its drug review timelines and business continuity despite sweeping staff cuts implemented under the Trump administration earlier this year, Paul Bridges, president of consulting at global CRO Parexel, told Jiho in a Tokyo interview.

The biopharmaceutical industry witnessed headlines of mass layoffs at the FDA in February-March this year as part of major headcount reductions executed across federal agencies under the new government.

The level of disruption at the FDA was unprecedented and initially raised concerns about the continuity of its review work, said Bridges. This prompted Parexel to set up a task force in March, tapping ex-FDA staff to track developments and advise clients in real time.

Analysis found, however, that most of the cuts were concentrated in divisions responsible for food, tobacco and certain medical devices, rather than the drug and biologics review centers. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) — the agency's two main drug review arms — were largely insulated from direct cuts because their operations are funded by user fees from industry.

Still, Bridges said voluntary departures have accelerated, particularly among experienced leaders. By the end of June, Parexel estimated more than 300 resignations at CDER and nearly 100 at CBER, with a further 500 scientific reviewers recusing themselves as they pursued outside opportunities. He warned that this kind of "brain drain" could weaken decision-making and delay reviews if it persists.

Bridges said the leadership drain was partly driven by workplace disruption under the new administration. The sudden revocation of the COVID-era remote work policy and a return-to-office mandate left some staff unable to secure desks or meeting rooms, creating frustration. Cuts to administrative support functions such as travel booking services also disrupted day-to-day operations. He noted that such turmoil likely pushed many experienced leaders to reconsider their careers outside the agency.

During the interview, Bridges pointed out that the industry's experience with Brexit gave it cause to be concerned about the disruption at the FDA. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) lost about a quarter of its workforce after Brexit, he said, adding that that exodus created significant backlogs in clinical trial approvals, led to a decline in trials conducted in the UK, and took about five years to recover.

For now, however, Parexel's internal monitoring suggests FDA performance remains on track. Review timelines have held broadly steady, with a rate of submissions missing target dates consistent with previous years, he said.

Bridges emphasized that Parexel's role is to help biopharma clients interpret such changes, adapt their strategies, and ensure continuity in getting medicines to patients. The company continues to advise sponsors to diversify regulatory engagement, seeking input not only from the FDA but also from regulatory counterparts in the EU, UK, Japan and others — agencies aligned with ICH principles — to mitigate potential risks.

Elsewhere, Bridges also noted a significant increase in the number of global companies looking to enter the Japanese market, driven by recent regulatory changes. Parexel Japan has seen an increase in the number of regulatory submissions it handles and has doubled its regulatory headcount to meet the demand. He said the shift reflects Japan's growing attractiveness as a launch market, which should help ease drug lag and expand patient access to innovative therapies.
