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US Regulatory Roundup, July 2019: A Quality Survey, Compliance Tips, A Raccoon Infestation, Industry's 'Perverse Incentive,' And More

by Shawn M. Schmitt

Handy tips from two US FDA facility investigators were of most interest to our online readers last month, but stories about the agency's Case for Quality initiative also attracted significant attention. Meanwhile, our coverage of a discovery by investigators of live raccoons and other animals at an Arkansas distributor's warehouses, and a concern by a Siemens cybersecurity expert that device-makers have "a perverse incentive" to not disclose cybersecurity vulnerabilities, was also widely read. Here are July's 10 most popular US regulation and policy stories from *Medtech Insight*.

Insights from US Food and Drug Administration investigators on process validation activities and handling nonconforming product were of high interest to *Medtech Insight*'s online readers last month.

The pair of *Compliance Corner* feature articles ranked Nos. 1 and 7 on our list of most-read stories in July. *In the first*, agency investigator Ben Dastoli revealed six common process validation mistakes that device firms make, *while the second* offered tips from investigator Thomas Peter on the best ways for companies to deal with problem products.

Also of significant interest to readers was the latest news on the FDA's Case for Quality Voluntary Improvement Program (CFQ VIP), used to measure a device-maker's manufacturing maturity and quality. The agency – with help from the Medical Device Innovation Consortium (MDIC) – uses a device industry-modified *Capability Maturity Model Integration* (CMMI) framework for its burgeoning initiative.

In our *No. 2 article* from July, Cisco Vicenty, the agency's *Case for Quality* program manager, said CFQ VIP has surprisingly been used to assess some pharmaceutical facilities. That's because some large manufacturers enrolled in CFQ VIP also have pharma plants under their corporate umbrella, and those firms are using the device-centered CMMI framework at their drug facilities to help drive continuous improvement there, too.

"They're enrolling pure pharma sites [in CFQ VIP]. Now, what we are going to do with that down the road, I'm not sure, but it's happening," said Vicenty, who noted that regulators from other countries have been reaching out informally to the FDA to learn more about CFQ VIP.

Meanwhile, in a textbook case of "do as I say, not as I do," a Thermo Fisher Scientific VP *urged more in vitro diagnostic manufacturers* to participate in CFQ VIP – despite his own IVD company not taking part.

Medtech Insight's *No. 5 story* in July was also related to Case for Quality, this time for an industry survey from MDIC that shows that a third of device firms are likely wasting money on quality efforts that are ineffective because they're not calculating the cost of quality.

And in one of the more bizarre stories in recent memory, an Arkansas distributor was ordered by the FDA to stop handling products that it regulates, including medical devices, after agency investigators found the company's warehouses teeming with insects, rodents, and other living and dead animals – including raccoons. *That story ranked No. 3* last month.

Readers also kept a sharp eye on goings-on at the Centers for Medicare and Medicaid Services. Our story on the CMS's *plan to boost new technology add-on payments* by 65% – even though industry groups want more – landed at No. 10 on our list. And July's *No. 8 article* explained why cardiologists and radiologists spoke in favor of new tech add-on payments for Boston Scientific's Eluvia drug-eluting stent, despite concerns about the device's paclitaxel coating.

Other articles of interest to readers included *a claim by Siemens AG's cybersecurity expert* that device-makers fear losing business by being transparent about cybersecurity vulnerabilities, pointing out that there's "a perverse incentive in some parts of the market that encourages a lack of disclosure," as well as *news that regulators are now one step closer* to making the FDA's precertification program a reality.

The 10 most popular US regulation and policy stories in July are listed in the table below.

Rank	Title
1	*Compliance Corner: These Are The 6 Top Process Validation Mistakes Made By Firms, According To An FDA Investigator*
2	*Catching Fire: FDA's Manufacturing Maturity Program For Devices Spreading*

	Internationally – And To Drug Facilities
3	*Live Raccoons, Dead Possum Bring Consent Decree To Arkansas Distributor*
4	*Siemens Cybersecurity Expert Says Medtech Industry Has 'Perverse Incentive' To Not Disclose Vulnerabilities – Might A New Law Be The Fix?*
5	*Survey Finds 1/3 Of Device Firms Don't Measure The Cost Of Quality. Here's How A Case For Quality Initiative Might Help*
6	*One Small Step For US FDA, But Maybe A Giant Leap For SaMDs*
7	*Compliance Corner: How A Firm Handles Nonconforming Products Can Make Or Break Its FDA Inspection, Investigator Says*
8	*Despite Paclitaxel Warnings, Physicians Endorse Boston Sci's Eluvia Stent For NTAP In CMS Pay Proposal Comments*
9	*Thermo Fisher VP Wants More IVD Firms Involved In FDA's Manufacturing Maturity Program (Even Though His Company Isn't)*
10	*CMS To Boost Medicare New Tech Add-On Payments To 65% – But Industry Wants More*