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Amneal Takes New Execs From Alvotech And FDA

Malki Joins As Quality Chief While Toufanian Heads Regulatory Strategy And Policy

by David Wallace

Amneal has looked to biosimilars developer Alvotech and the US FDA's Office of Generic Drugs for its latest executive appointments, with Reem Malki joining the US firm as chief quality officer and Maryll Toufanian becoming head of regulatory strategy and policy.

Amneal has announced the appointment of two new executives to its leadership team, with former *Alvotech* chief quality officer Reem Malki joining Amneal in the same capacity, at the same time as the US Food and Drug Administration's former director of the office of generic drug policy, Maryll Toufanian, has been named as Amneal's head of regulatory strategy and policy. Both have been made senior vice-presidents.

Amneal said the move "deepens [our] leadership experience and capabilities to drive key growth areas of biosimilars, complex generics, injectables and specialty."

Malki had recently left Alvotech, replaced by Sarah Tanksley in mid-October, with the biosimilars developer explaining that Malki was "stepping down for personal reasons" (*see sidebar*).

Amneal said she "brings over 30 years of quality operations and regulatory experience in the pharmaceuticals industry," citing her responsibility at Alvotech "for all quality functions advancing the company's growing

Who's Hired? Alvotech Brings In New Quality Chief

GENERICS BULLETIN
CITELINE COMMERCIAL

biosimilar pipeline."

Prior to joining Alvotech, Malki held various senior leadership roles at Mylan – including head of global quality operations and vice-president of EMEA quality operations – before which she held "increasing responsibility in quality control at Andrx Pharmaceuticals leading up to its acquisition by Watson Pharmaceuticals, most recently as director of quality control."

By David Wallace

14 Oct 2022

Alvotech has appointed a new chief quality officer in the wake of manufacturing deficiencies being identified by the US FDA. Meanwhile, multiple executives have departed from Hikma's management team, with one joining Lupin as chief scientific officer.

Read the full article here

Meanwhile, Toufanian joins Amneal from the FDA's Center for Drug Evaluation & Research where her role as director of the office of generic drug policy involved "overseeing all regulatory and policy matters of the Office of Generic Drugs' generic drug program, including the development and implementation of regulations, guidance, policy statements, and publication of FDA's Orange Book."

Describing Toufanian as "a nationally recognized expert in drug regulation," Amneal noted that she had also previously held various other senior leadership roles with the FDA, including as acting deputy director for clinical and regulatory affairs for the OGD; deputy director of the office of generic drug policy; director of the division of legal and regulatory support for the OGD; principal advisor to the deputy commissioner for the FDA's office of policy, legislation and international affairs; and as associate chief counsel for drugs for the FDA's office of chief counsel. Prior to joining the FDA, Toufanian served as an associate with Zuckerman Spaeder LLP, specializing in food and drug and criminal defense matters.

Amneal co-CEOs Chirag Patel and Chintu Patel said they were "so excited to welcome Reem and Maryll to our leadership team."

"In this next phase of growth for Amneal, we are significantly expanding in high growth areas such as biosimilars, complex generics, injectables and specialty," the Patels noted. "Reem and Maryll bring deep expertise that will be invaluable as we go forward and expand Amneal in these more complex areas."

Follows Amneal's First Biosimilar Launch

The appointments come soon after Amneal launched its first biosimilar, the Alymsys (bevacizumab-maly) rival to Avastin, in the US (*see sidebar*).

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Along with the FDA-approved Releuko (filgrastim-ayow) and Fylnetra (pegfilgrastim-pbbk) biosimilars – expected to launch by the end of the year – Amneal foresees "peak sales for these three US biosimilars of $200m" within the next couple of years. (Also see "*Amneal Sets $200m Sales Ambition For Biosimilar Trio*" - Generics Bulletin, 12 May, 2022.)

Commenting after her appointment, Malki said Amneal could boast "a very impressive quality track record over its 20-year history," adding that "as the company expands into new growth areas, we will strive to maintain that industry-leading quality reputation. I look forward to leveraging my biopharmaceuticals experience, particularly as Amneal grows in biosimilars."

Meanwhile, Toufanian said she was "pleased to join the Amneal team at an exciting time in its growth trajectory. Across the company's pipeline, I look forward to contributing my regulatory expertise to continue strengthening Amneal's product launch and commercialization strategies. I will also ensure the company's voice is heard on key policy issues affecting our business."

Amneal Makes First Biosimilar Launch With US Bevacizumab

By David Wallace

07 Oct 2022

Amneal says it has "officially entered the US biosimilar market" after introducing its Alymsys biosimilar bevacizumab rival to Avastin. The biosimilar launch represents the first of three expected for Amneal in 2022, following US FDA approvals earlier this year.

Read the full article here