



## **AstraZeneca and MRC Form Groundbreaking Scientific Collaboration That Will Advance Medical Research**

The United Kingdom's (UK) Medical Research Council (MRC) has formed a groundbreaking partnership with AstraZeneca which will provide UK academic researchers free access to 22 high-quality AstraZeneca compounds. The collaboration will allow academia to be funded by MRC and to conduct studies to better understand disease mechanisms, ultimately to help develop new treatments. The landmark initiative will allow AstraZeneca to work with a larger portion of the academic community and to be involved in disease treatments outside of the company's typical concentration.

As part of the collaboration, the MRC is inviting research proposals from across the UK academic community to use the AstraZeneca compounds in new areas. The MRC will judge and select the best scientific proposals and will award up to a total of £10 million (\$15.6 million). "The initiative marks a new era in medical discovery, open innovation and public-private collaboration," said Sir John Savill, MRC's chief executive, in a press release.

## **FDA Warns Novartis of Violations at Three Plants**

The FDA issued a warning letter to Novartis for their Sandoz, Inc. generic drug manufacturing facilities, citing "significant violations" of CGMP regulations during three inspections at the company's units in Broomfield Colorado; Wilson, North Carolina; and Boucherville, Canada. The Agency stated that the company had failed to correct repeated manufacturing violations. After inspecting the facilities between April and August of 2011, FDA determined violations that included failure to submit NDA Field Alert Reports for bacterial contamination; failure to establish or follow written procedures to prevent microbiological contamination, including validation of the sterilization process; failure to investigate out-of-specification batches; and failure to have adequate written procedures for production and process controls designed to assure that the drug products manufactured had the identity, strength, quality, and purity they needed.



Other examples cited in the warning letter were that media fill studies were insufficient to establish that the aseptic process was in control, and that the company failed to follow their procedures for the validation of their aseptic process in the Canada operation. In their North Carolina facility, process validation for several drug products was not adequate. FDA noted that at the Boucherville facility, it was “concerned that your firm lacks process understanding to consistently manufacture” the product. The agency added, “It is apparent that Novartis International AG (Novartis) is not implementing global and sustainable corrective actions.”

## **FDA and EMA to Begin Joint Manufacturing Inspections**

The FDA and the EMA will begin sharing facility inspection data in their respective territories in January 2012 to make better use of resources and reduce drug makers’ inspection burdens. The initiative will allow the authorities’ inspection capacity to shift to other regions, which is a particularly constructive change, as companies shift their bases away from the US and Europe. The program will allow the two agencies to use each other’s inspection outcomes instead of having to perform duplicate inspections. The two authorities will establish a master list of API supply facilities, as well.

The plan will concentrate on sites that the FDA and EMA already know and that have complied with good manufacturing practices, which will enable the agencies to work more efficiently. The EMA stated that the changes would probably only affect routine post authorization/surveillance inspections; pre-authorization/pre-approval inspections are expected to remain mostly unchanged. The agencies will review the initiative after three years.