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ASIA EDITION

US FDA issues a warning letter to Hospira

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Singapore: Hospira plant in Australia, that makes specialty injectable drugs, has received a warning letter from the US FDA for manufacturing and quality issues. During an inspection of the drugmaker's manufacturing facility located at Victoria, the FDA found incomplete investigations of out-of-specification results, for multiples batches of the injectable cancer drug mitoxantrone.

Hospira officials said that they took the letter very seriously and were working diligently to get them resolved. The company has faced quality issues at its US, and more recently at its India manufacturing sites. Earlier this year, Hospira CEO, Mr F Michael Ball, told analysts that after a pre-approval inspection of a plant it is building in Vizag, India, the FDA issued a Form 483 with 10 observations.

During the second quarter of 2014, Hospira enjoyed some relief when the FDA came up with no observations after re-inspecting the company's Rocky Mount manufacturing facility. This is an important milestone for Hospira, which will allow the company to start producing at the pre-shortage.

Recently Hospira stated that it was implementing a global corrective action plan to solve issues at its manufacturing facilities both in India and abroad. However, the warning letter pertaining to the Australian facility has added to the company's list of challenges which it needs to overcome.