

New Hampshire Bio/Med Council Best In Bio Series

2010-06-10

The New Hampshire Bio/Medical Council has scheduled a world class panel to discuss recent changes in FDA compliance and enforcement. FDA inspection - R U Ready? is the second in the Best in Bio Series of educational events and will be held on June, 10 in Portsmouth, New Hampshire.

The Food and Drug Administration (FDA) has announced that it plans to increase criminal prosecutions of individual corporate executives under the strict liability misdemeanor provision of the Food, Drug, and Cosmetic Act (FDCA). The announcement is consistent with recent cases in which the FDA and the Department of Justice have brought misdemeanor criminal charges against high-level executives who historically would not have been prosecuted because they neither participated in nor knew of illegal conduct.

The New England District office of the FDA has recently added 3 new Compliance Officers bringing the total to 10. A major New England based device company recently pled guilty to two misdemeanors and agreed to pay \$296 million in fines...the biggest fine ever imposed on a device manufacturer by the FDA.

Karen Green, partner in the Litigation/Controversy Department is speaking at this event.

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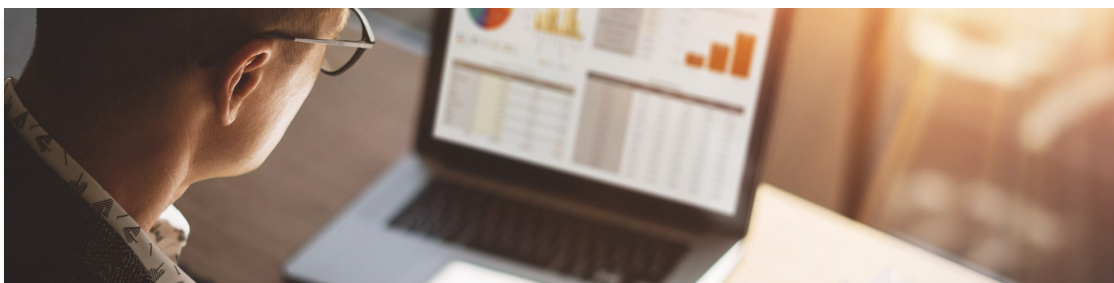
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