PharmaTech – Recall of liquid products

- On August 8, 2017, the FDA announced that patients, pharmacies and healthcare facilities should immediately stop using and dispensing **all** liquid products manufactured by PharmaTech due to *Burkholderia cepacia* contamination and the potential for severe patient infection.
- The FDA also announced a voluntary recall of Rugby's Diocto Liquid and Diocto Syrup, both oral liquid docusate products, manufactured by PharmaTech.
- Additional liquid drug products manufactured by PharmaTech might also be affected. Such products might have been labeled and distributed by Rugby and other companies, which might be more difficult to determine since they are not labeled with a PharmaTech label.
- The Centers for Disease Control and Prevention (CDC) laboratory testing of PharmaTech's oral liquid docusate detected a strain of *B. cepacia* bacteria linked to recent patient infections. Therefore, the FDA recommends healthcare professionals and patients not use PharmaTech's liquid drug products.
- The FDA advises healthcare facilities and pharmacies that think they might have liquid PharmaTech drug products, especially oral liquid docusate drug products, to check with their supplier to determine the identity of the manufacturer.
- Patients who are using liquid drug products and who have concerns should contact their healthcare professional.
- Any company that purchased liquid products manufactured by PharmaTech should immediately quarantine material under their control and contact the local FDA pharmaceutical recall coordinator.
- The FDA reminds manufacturers of the importance of robust manufacturing and testing of liquid products to ensure low levels of microorganisms and the absence of any that might cause infection.
- In 2016, the FDA advised health care professionals and patients not to use liquid docusate drug products manufactured at PharmaTech's facility after being implicated in the CDC's public health investigation. These products were labeled and distributed by multiple companies, including Rugby.
    - An FDA investigation associated with a 2016 multistate outbreak identified *B. cepacia* in more than 10 lots of oral liquid docusate sodium manufactured by PharmaTech, which was linked to patient infections that required intensive medical treatment. The 2016 investigation also detected *B. cepacia* in the water system used to manufacture the product.