



UNIVERSITÀ DEGLI STUDI DI MILANO

DIPARTIMENTO DI  
SCIENZE FARMACEUTICHE

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## *Corso di Laurea Magistrale in Chimica e Tecnologia Farmaceutiche – E25*

### *Fabbricazione Industriale dei Medicinali – 4 CFU*

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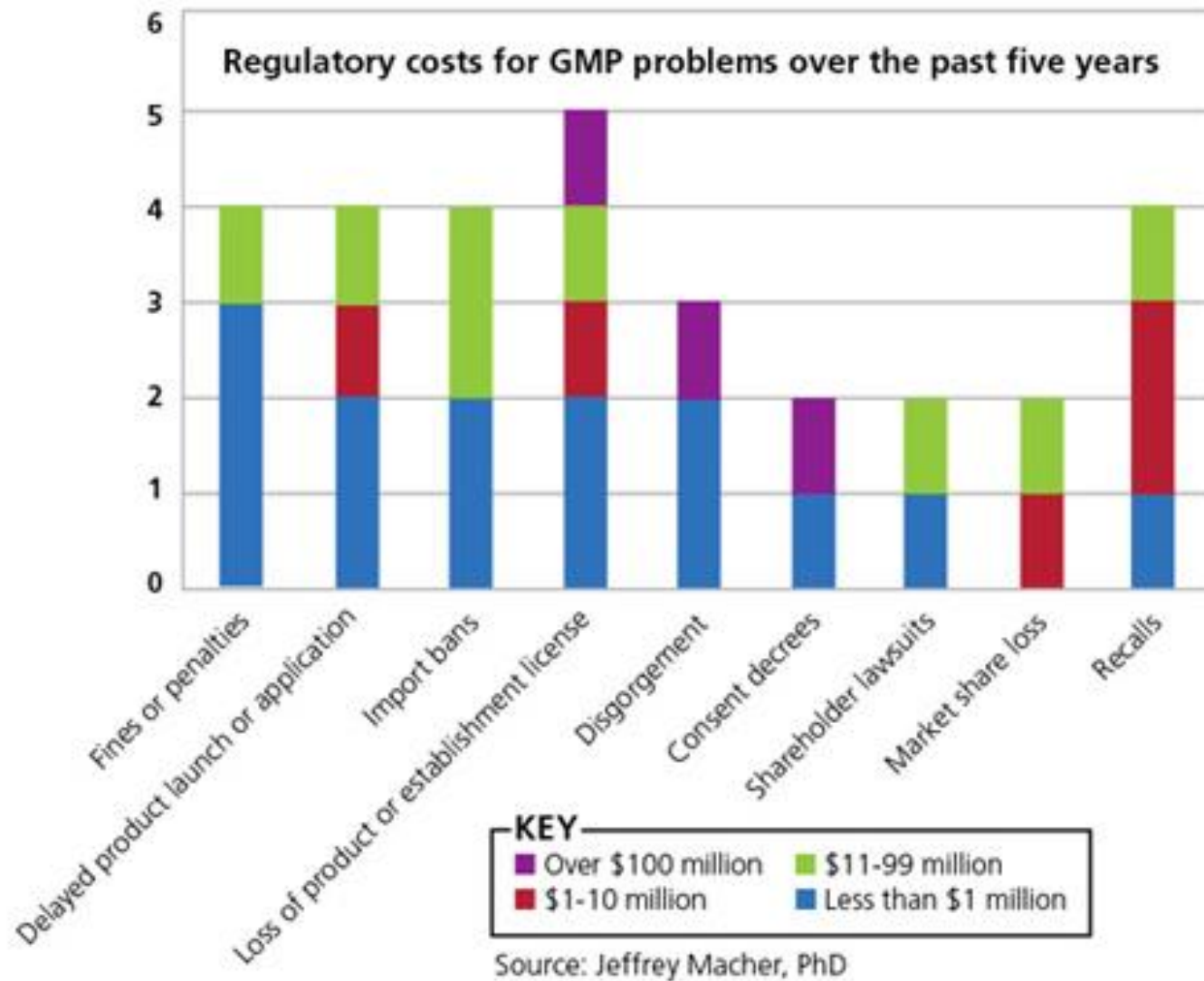
*Brevi riflessioni sul programma finora svolto (12-11-2014)*

*Dott. Marco Adami*

# Riflessioni del 12 Novembre 2014

## ➤ The cost of poor quality

- ✓ Quality problems present the public with huge potential costs
- ✓ For manufacturers, there are potentially **huge external** costs (for delayed product launches or approvals, severe actions such as consent decrees) AND the **intangible costs** of loss of reputation
- ✓ Less dramatic are the **internal costs** (wasted raw materials, rejected batches, and the cost of investigations and remediations)



# The cost of poor pharmaceutical manufacturing quality systems

- Survey sponsored by PDA and ISPE (Fall 2013)
  - ✓ 70 professionals (19 manufacturing companies, 37 facilities, and over 150 products)
  - ✓ 12% had incurred regulatory costs due to GMP deficiencies
  - ✓ 62% did not calculate the cost of poor quality at their production sites
  - ✓ Roughly 92% did not evaluate the cost of improving quality against the potential cost of failure

# The cost of poor pharmaceutical manufacturing quality systems

## ➤ Reason to look out for poor quality

- ✓ It makes good business sense and leads to improvements
- ✓ In the survey, those who had begun efforts to measure the cost of poor quality had already begun to see some improvements (better on-time delivery, reduced internal failures and deviations, overall cost savings of over 15%)
- ✓ Key points
  - Training and use of IT to collect, analyze and report on poor quality costs
  - To make corrective processes possible to operators and those doing the work, so that changes can be made during manufacturing