Coronavirus Pandemic
PDA Israel Chapter
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PDA Activities due to Covid -19

- two task force were initiated:
  - **Covid-19 response** : podcasts, webinars, papers
    - PDA COVID-19 Task Force Podcast Series can be found:
      At the following link: https://anchor.fm/pda-covid-19-tf
  - **Audit and Inspection**:

1. *Webinars*-such as
   - Characteristics/survivability Impact of the Covid-19 Pandemic on the pharmaceutical supply chain
   - Remote Regulatory Assessment and Inspections-Industry Perspective
   - Remote supplier and internal auditing – general
   - Remote supplier and internal auditing – technology Jan.22, 2021

PDA Activities due to Covid -19

- **Audit and Inspection**:

2. *Points to Consider Documents*

- Aspects covered:
  - Cultural/Communication
  - Legal Aspects and DI
  - Technology
  - Determining Audit Type Using a Risk-Based Approach

Points to Consider in Remote Virtual and Hybrid Audits

- The global travel restrictions have impacted the ability of the pharmaceutical industry to conduct audits to aid in timely detection and remediation of non-compliance.
- Industry has quickly pivoted to the design and implementation of remote audits to ensure the requirements of Health Authorities and marketing authorizations are met.
- The objective of this document :
- introduce a standard nomenclature when describing remote audits,
- describe the steps taken to ensure an effective and efficient assessment: Definitions, Scheduling, Duration, Planning, Conduct, Closing and Wrap-up, Reporting, Follow-up and References.

Points to Consider in Remote and Hybrid GMP/GDP Inspections

Globally, health authorities have increased their use of remote inspections due to COVID-19 precautions. If remote inspections can provide thorough and reliable information, health authorities may continue to use them in certain situations in the future. While on-site inspections continue to be the optimal way to assess compliance, remote inspections allow for increased involvement of specialized experts, from both the inspected and the inspectorate perspective, to support specific aspects of the assessment in a way that has not traditionally been possible in on-site inspections. Remote inspections also offer other advantages, including the reduction in costs and travel burdens. PDA believes that some of the practices developed as a result of COVID-19 may continue to be useful well into the future, as they may allow for more comprehensive oversight and for optimal use of regulatory resources, based on risk.

Example of Risk Assessment

Auditable Entitee	Auditable Entity Criticality	Historical Audit Performance	Placeholder	Regulatory Compliance History	Overall Risk Score	Justification
Company C	Critical	High	L3	Low	Medium	Company C is a sterile manufacturer, resulting in critical manufacturing type. Recent audit history includes critical findings, resulting in high rating for audit performance. Recent regulatory inspections resulted in no findings, resulting in a low rating for regulatory compliance history.
Company D	Minor	Medium	L1	Low	Low	Company D is a back up contract testing laboratory, resulting in a minor manufacturing type. Recent audit history includes no critical but some major findings, resulting in medium rating for audit performance. Recent regulatory inspections resulted in no findings, resulting in a low rating for regulatory compliance history.
Company E	Critical	High	L3	High	High	Company E is a contract sterility testing laboratory, resulting in a critical manufacturing type. Recent audit history includes critical findings, resulting in high rating for audit performance. Recent regulatory inspections resulted in findings with further action expected, resulting in a high rating for regulatory compliance history.

Commenting on guidelines and Discussions

- Absenteeism

- Cov-19 Infections in Employees

Absenteeism

Guidance for Industry

Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products

March 2011

Cov-19 Infections in Employees

Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing

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Guidance for Industry

June 2020

Example of a conclusion of a specific Risk Assessment performed

- The Generic Risk Assessment for **SARS-CoV-2/Covid-19,** with the objective to assess the procedures and measures in place to mitigate the risk of SARS CoV-2 contamination of pharmaceutical products

- The conclusion of the Assessment says that **Considering a negligible likelihood of hazard occurring and a low consequence of hazard, the risk of SARS-CoV-2 product contamination is considered as negligible**.
- **Based on these facts, no additional measures are needed in addition to existing GMP-conforming procedures within the manufacturing sites.**

- Nonetheless, in the event an employee is tested positive is found within the GMP environment, a Deviation needs to be initiated to document the specific risk assessment to analyze and assess any issue that might need to be considered based on the specific circumstances.