



IX PAN-RUSSIAN  
GMP CONFERENCE



MINISTRY OF INDUSTRY  
AND TRADE OF RUSSIA



# 中国药品远程检查的探索与实践

## The Exploration and Practice of Remote Inspection In China

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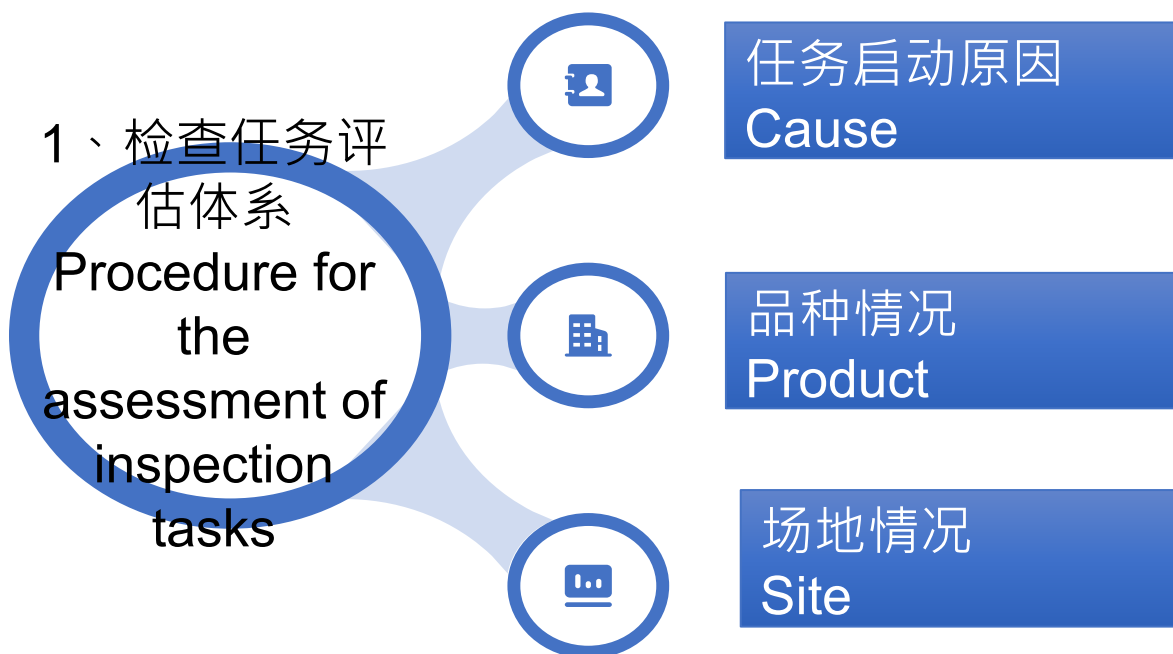
小结与展望  
Summary and Expectation

- 我国药品远程检查的探索始于2020年，由于新冠疫情造成的人员流动限制和防护风险，使得药品现场检查，尤其是境外药品生产现场检查，面临诸多困难，难以正常开展。为应对此挑战，核查中心开始探索在境外药品生产企业的检查中采用远程检查方式。境外检查中的远程检查实践，部分弥补了疫情期间正常药品现场检查工作缺失带来的影响。
  - The exploration of remote inspection of drugs in China began in 2020. Due to the restrictions on mobility and personnel protection risks caused by the COVID-19, on-site inspection of drugs, especially overseas on-site inspection, faces many difficulties and is hard to carry out normally. In response to this challenge, CFDI begun to explore the use of remote inspection methods in the inspections of overseas pharmaceutical production enterprises. The remote inspection practice in overseas inspections has partially compensated for the impact of the lack of normal on-site drug inspections during the epidemic.
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- 远程检查方式在境外检查中具有部分特殊优势，疫情管制结束后，基于风险评估，仍有部分任务采用远程方式开展。
  - The remote inspection method has shown some advantages in overseas inspections. After the end of epidemic control, based on risk assessment, some tasks are still carried out by remote inspection.

### (一) 制度体系构建

#### Construction of Procedures

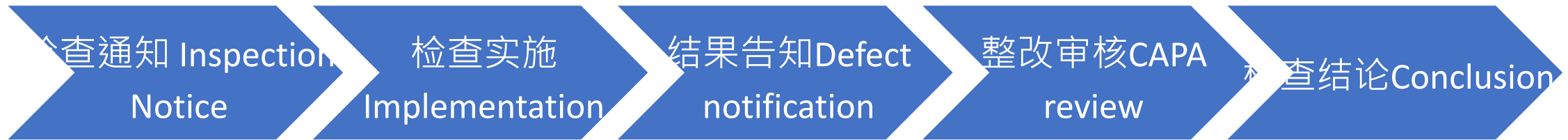
为保证境外药品生产企业远程检查工作规范开展，核查中心探索建立了一系列相关制度措施，包括：  
To ensure the standardized implementation of overseas remote inspection, CFDI has explored and established a series of relevant procedures, including:



## 二、远程检查的探索实践 The Exploration and Practice of Remote Inspection



### 2、工作流程 Inspection Procedure



检查前40日发出检查通知及资料清单

Inspection notice and a list of required documents will be sent out 40 days before inspection

3-5个工作日  
检查组集中进行文件记录检查、视频检查及沟通、基于问题进一步沟通及索取证明资料

The inspection team will spend 3-5 days to conduct document checks and video checks, based on the findings, further documents may be requested.

检查结束后20个工作日发出，异议反馈10工作日

Defects list will be sent out within 20 working days after the inspection, and if the enterprise has any objections, it can provide feedback within 10 working days

50工作日  
CAPA

The enterprise should submit CAPAs in 50 working days

符合  
整改后符合  
不符合

Based on the CAPAs submitted by the enterprise, the conclusion may be either compliant, compliant after rectification, or non compliant

### 3、检查资料清单

List of required documents

基本信息  
Basic information

程序文件  
Procedures

原始记录  
Records

图纸  
Drawings

- 生产车间平面图，包括洁净级别、人流与物流标识
- 库房平面布局图
- 质量控制实验室平面布局图

录像视频  
Videos

- 按照物流走向从物料接收、取样、放行、分发、关键生产工序、中控取样、包装入库全流程的代表性视频文件；
- 最近一次对应生产线培养基模拟灌装试验录像；
- 生产区A级环境气流烟雾试验录像；

### (二) 检查实施情况 The Practice of Remote Inspection

序号	生产工厂	国家
1	Kagamiishi Plant, Nipro Pharma Corporation	Japan
2	Dr.Reddy`s Laboratories Limited	India
3	Gilead Sciences Ireland UC	Ireland
4	Wyeth Lederle S.R.L.	Italy
5	Pfizer Ireland Pharmaceuticals	Ireland
6	JW LIFE SCIENCE CORPORATION	South Korea
7	Vianex S.A.—Plant C	Greece
8	澳美制药厂	Hong Kong
9	UCB Pharma S.A.	Italy
10	Pharmacia & Upjohn Company	America
11	Sun Pharmaceutical Industries Limited	India
12	GlaxoSmithKline (Ireland) Limited	Poland
13	Cephalon Inc.	Netherlands
14	Hetero Labs Limited	India
15	Pfizer Limited	Germany、Ireland
16	CHEPLAPHARM Arzneimittel GmbH	Denmark
17	ALMIRALL,S.A.	Spain
18	Sandoz Inc	SLOVENIA
19	Hetero Labs Limited	India
20	BIOTON S.A.	Poland

2020年至2023年对20家次境外药品生产企业开展了远程检查。

### 三、小结与展望 Summary and Expectation



#### 优势 Advantages

1

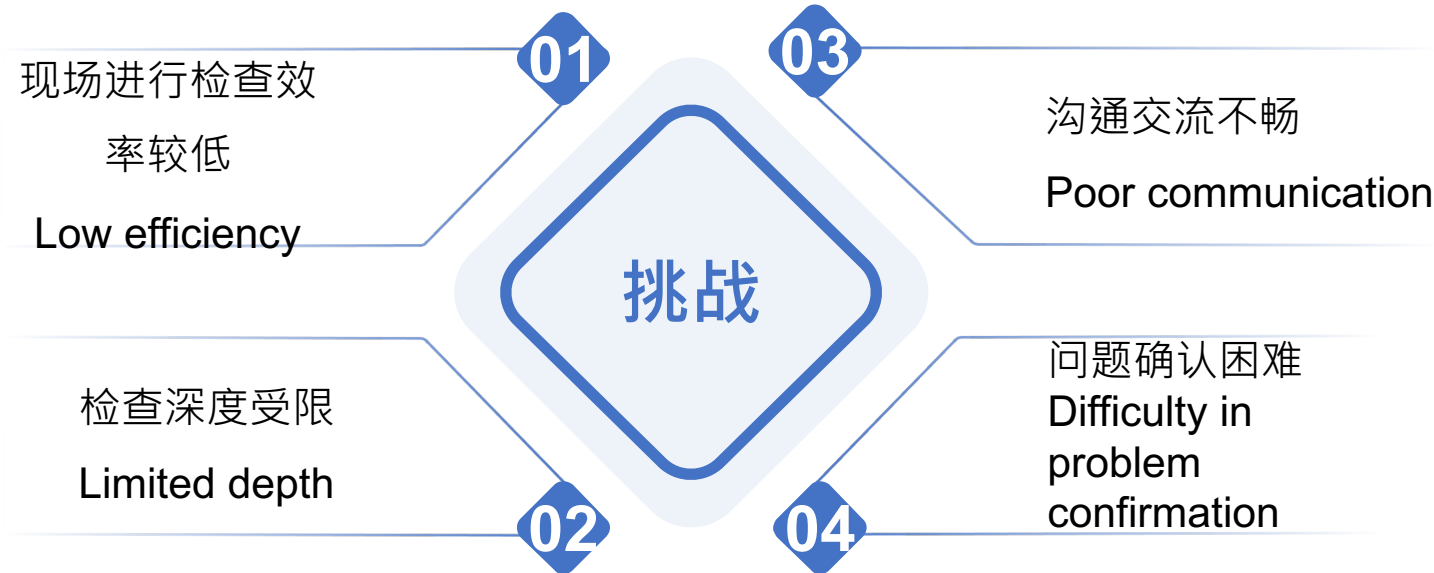
免除了出境手续  
Avoid the complex procedures for going abroad

2

减少了路程中耗费的时间  
Saved the time spent on the journey

3

及时开展  
Inspection can be carried out in a timely manner



远程检查不能替代现场检查，结合任务类型、技术手段、企业数据电子化程度等情况，有限度的开展远程检查。

Remote inspection cannot replace on-site inspection. Based on the type of inspection, technical means, and the degree of electronic data in the enterprise, remote inspection can be carried out in a



Thanks for your attention 感谢！

**像守护亲人一样 守护公众健康！**

**Safeguard the public health as our beloved ones!**

A blue rectangular banner with a white border. On the left is a large QR code with a small CFDI logo in the center. Below the QR code is the text '长按扫描图中二维码'. To the right of the QR code is the CFDI logo, which consists of a stylized human figure in blue and purple, followed by the letters 'CFDI' in a bold, blue, sans-serif font. Below the logo is the text '维护和促进公众健康 确保用药安全有效'. At the bottom of the banner, centered, is the text '国家药品监督管理局食品药品审核查验中心'. Below this, on the left, is a location pin icon followed by the address '地址：北京市西城区文兴街1号院3号楼北矿金融大厦6层'. On the right is a telephone icon followed by the phone number '电话：010 68441000'.

长按扫描图中二维码

**维护和促进公众健康  
确保用药安全有效**

国家药品监督管理局食品药品审核查验中心

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