**CFDA Notification concerning the issues of Product Technical Requirement**

CFDA Notification No 22-2016

Released on Mar 1, 2016

Summary in English:

This notification is to clarify the issues concerning with the Product Technical Requirement (PTR) according to the State Council’s Order #650.

1. Manufacturer shall produce/supply the product registered strictly according to the mandatory standards applied as well as the PTR filed/registered with CFDA. When submitting for product registration, the manufacturer shall submit the PTR with the test methods verifying the specification in PTR for the final product.
2. Manufacturer (registration applicant) shall composite and submit the PTR including technical specifications of final product and the correspondent test methods, when applying for the product registration.
3. The test institute shall conduct the testing according to the PTR submitted. Meanwhile, the test institute shall pre-evaluate the PTR prepared by the manufacturer and give comment(s) according to CFDA process and requirement of pre-evaluation (CFDA Notification No 192-2014).
4. CFDA-CMDE shall do final review and evaluation on safety and performance based on the PTR submitted and eventually give the reviewing decision
5. PTR consists of final product specifications and the test methods through which to verify each of all the specifications. PTR does not specify which specifications should be tested on the product for final release or delivering from production line. However, the manufacturer shall establish the clear testing schemes in production steps based on PTR, product character, manufacturing process and working flow, and quality management system. The testing schemes shall be doable and stable in the practical operation, so that the products tested in production steps and finally released meet the mandatory standards and the PTR registered with CFDA.

When the manufacturer find any incompliance with the mandatory standards or PTR, or any default of the product, shall stop the production, notify the distributor(s), users and customers to stop the distribution and use. Recall its product and take any necessary measures, and report to CFDA and Health authorities.

1. Food & Drug Administrations national-wide shall be responsible for the supervision of the local manufacturers, and importantly, check whether or not the production is controlled and required according to the mandatory standards and the PTR registered and verify the compliance of the products with the mandatory standards and PTR. Specifications and the test methods provided in PTR may be taken as the criteria or standards to verify the compliance of the product.
2. CFDA will in cooperate with other authorities under the State Council, give accreditation and training for the test institutes in order to do compliance verification with PTR. PTR including the specifications and test methods will be taken by accredited test institute to be used for routine inspection of product quality.

In Chinese

总局办公厅关于医疗器械产品技术要求有关问题的通知

食药监办械管〔2016〕22号

2016年03月01日

各省、自治区、直辖市食品药品监督管理局:

　　为贯彻实施《医疗器械监督管理条例》（国务院令第650号，以下简称《条例》），进一步明确产品技术要求有关问题，现将有关事项通知如下：

一、《条例》中明确了产品技术要求的法律地位。第一类医疗器械产品备案和申请第二类、第三类医疗器械产品注册，应当提交产品技术要求等资料；医疗器械生产企业应当严格按照经注册或者备案的产品技术要求组织生产，保证出厂的医疗器械符合强制性标准以及经注册或者备案的产品技术要求。

二、医疗器械注册申请人应当根据医疗器械成品的性能指标和检验方法编制产品技术要求，在注册申请时提交产品技术要求及其他注册申报资料。

　　三、承担注册检验的医疗器械检验机构应当依据产品技术要求对相关产品进行注册检验，并根据《食品药品监管总局关于印发医疗器械检验机构开展医疗器械产品技术要求预评价工作规定的通知》（食药监械管〔2014〕192号）的要求，对注册申请人提交的产品技术要求进行预评价。

　　四、医疗器械技术审评机构在对申请注册医疗器械技术审评时，应当根据产品技术要求及其他注册申报资料，对其安全性、有效性研究和结果进行系统评价，提出结论性审评意见。

五、产品技术要求主要包括医疗器械成品的性能指标和检验方法，其中哪些项目需要出厂检验，不在产品技术要求中规定。企业应当根据产品技术要求、产品特性、生产工艺、生产过程、质量管理体系等确定生产过程中各个环节的检验项目，最终以产品检验规程的形式予以细化和固化，用以指导企业的出厂检验和放行工作，确保出厂的产品质量符合强制性标准以及经注册或者备案的产品技术要求。

　　医疗器械生产企业发现其生产的医疗器械不符合强制性标准、经注册或者备案的产品技术要求或者存在其他缺陷的，应当立即停止生产，通知相关生产经营企业、使用单位和消费者停止经营和使用，召回已经上市销售的医疗器械，采取补救、销毁等措施，记录相关情况，发布相关信息，并将医疗器械召回和处理情况向食品药品监督管理部门和卫生计生主管部门报告。

　　六、食品药品监督管理部门应当加强本行政区域医疗器械生产企业的监督检查，并对医疗器械生产企业是否按照经注册或者备案的产品技术要求组织生产等事项进行重点监督检查。产品技术要求是载明产品性能指标和检验方法的文件，可作为监督抽验的抽验依据。

　　七、产品技术要求是针对一个具体注册申报产品制定的，依据产品技术要求认可医疗器械检验机构检验资质，不能解决承检范围覆盖问题，按照检验项目和参数进行检验机构资质认定，可以满足注册检验和监督抽验的要求，符合监管工作需求。总局将积极协调，依法配合国务院有关部门推进医疗器械检验机构资质认定工作，并加强对相关检验机构资质认定工作的培训和指导。

食品药品监管总局办公厅

2016年2月26日