■ 招待講演1

演者： 松田 嘉弘（独立行政法人医薬品医療機器総合機構　スペシャリスト（品質担当））

連続生産（Continuous Manufacturing）

連続生産は革新的な製造技術として世界的に注目を集めており、PMDA、US FDA、EMA は医薬品製造への連続生産技術導入へのサポートを表明している。特に日本においては、PMDA 内に革新的製造技術 WG を立ち上げるとともに、AMED 研究として連続生産に関する検討も進めており、これまでに複数の研究成果物を公開してきた。ICH においても、ICH Q13 として医薬品連続生産が新規トピックとして採択され、また日本においても連続生産技術を用いた医薬品が 2018 年 9 月に承認されるなど、連続生産を取り巻く環境は急激に進展しつつある。本講演ではこれまで PMDA が関与してきた研究成果物、実際に承認した医薬品連続生産に関する内容について、公開されている審査報告書を基に紹介したい。

■ 招待講演 2

演者： 工藤　俊明（厚生労働省医薬・生活衛生局　監視指導・麻薬対策課）

改正 GMP について

医薬品及び医薬部外品の製造管理及び品質管理の基準については、医薬品医療機器等法第 14 条第2項第4号に基づき、GMP 省令により規定している。今般、PIC/S の GMP ガイドライン等の国際基準との整合化推進に加え、従前より GQP 省令、施行通知等により示している事項について、GMP 省令に規定する等の一部改正を行う予定であり、その改正の概略と趣旨について説明する。

■ 特別講演 1

演者： Richard M. Johnson（President and CEO, Parenteral Drug Association）

Current Issues in Pharmaceutical Manufacturing

– A Global PDA Perspective

Pharmaceuticals are changing by: location of manufacturing and markets supplied; types of products produced; and regulatory expectations. This presentation will discuss these trends. Pharmaceutical manufacturing is increasingly global, and the focus is on smaller batch sizes and platform technology. More of the newer products are biologic, while more access in developing world is increasing demand for legacy products while also increasing price pressures. Regulatory oversight is expanding, and requirements are becoming more strict.

■ 特別講演 2

演者： Thomas O’Connor（US Food and Drug Administration Senior Chemical Engineer, Division of Product Quality Research, Office of Testing and Research Member of Emerging Technology Team）

Emerging technology: A key enabler for modernizing pharmaceutical manufacturing and advancing product quality

Over the past decade, there has been substantial progress towards modernizing pharmaceutical manufacturing. However, at the same time, pharmaceutical manufacturing continues to confront a number of challenges, which result in unacceptably high occurrence of product quality issues. Nearly two thirds of all drug shortages relate to quality issues surrounding product manufacturing or facilities. These quality issues expose patients to unnecessary risk and negatively impact public health. Working with industry to encourage the modernization of pharmaceutical manufacturing technology is a mutually beneficial approach to increase manufacturing efficiency, improve overall drug quality, avoid shortages, and prepare for future regulatory challenges.

To encourage the adoption of innovative approaches in pharmaceutical manufacturing and to prepare for reviews and inspections involving technology for which there is little experience, the Agency established the Emerging Technology Program. This program features a cross–functional Emerging Technology Team (ETT) which works directly with industry to identify and resolve potential scientific and policy issues that may impact technologies new to the pharmaceutical industry. In a relatively short period of time, the Emerging Technology Program has facilitated the approvals of the first 3D–printed drug product, the first drug product made via continuous manufacturing, and the first switch to a continuous manufacturing process for an approved drug product.

In this talk, FDA's emerging technology program is described including a summary of industry interactions and observed trends. Approximately 50% of all ETT and industry interactions have been to continuous pharmaceutical manufacturing. FDA's regulatory approach for CM is then discussed to illustrate FDA's emerging technology program to support innovation.