Work Group Charter: Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

WORK GROUP TOPIC:

Human cells, tissues, and cellular and tissue-based products (HCT/Ps) are widely used in healthcare. Most of these products are regulated as biologics, but some products fall within the scope of medical devices.

WORK GROUP LEADERS:

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CHARTER:

The work group will focus on the tracking of medical devices containing HCT/Ps through the entire supply chain and will engage participants from all parts of that chain to develop educational material and guidance to address the issues described above.

BACKGROUND:

Human cells, tissues, and cellular and tissue-based products (HCT/Ps) are widely used in healthcare. Most of these products are regulated as biologics, but some products fall within the scope of medical devices.

HCT/Ps have unique characteristics that have implications throughout the supply chain. In particular, it is important to recognize that:

- A single donor can be the source of many different products, for example, one donor may donate skin, tendons, heart valves, and a wide range of bone products. All of these different products share a common history.
- Some of the products prepared from one donor may fall within biologics regulation while other products from the same donor fall within medical device regulation.
- HCT/Ps carry a risk of disease transmission. While this risk is minimized by testing and processing, it can never be entirely eliminated.

A single donor's tissues and cells may be recovered and sent to more than one tissue/cell processor, and this donated material can be distributed across multiple product lines. The highest element in the hierarchy in this scenario is the human donor. Other levels of the hierarchy include the identification of the donation event, the tissue processor, and the product/catalogue number and the serial number of the individual products prepared.

It is imperative that following detection of disease transmission caused by an HCT/P, all other products (biologics and medical devices) derived from the same donor can be rapidly removed from the supply chain and all patients who have received products from the donor can be followed up.

HCT/Ps and the Distinct Identification Code

The traceability model for HCT/Ps has unique characteristics that are not present for other healthcare products. In particular, an identifier is required to allow tracking from recipient to donor and from donor to recipient. FDA regulation uses the term distinct identification code – see 21CFR 1271.290(c).

The distinct identification code needs to be captured at all point in the supply chain in order to allow rapid tracking and recall of all the products (biologics and medical devices) derived from the implicated donor. The UDI Final Rule requires that medical devices containing HCT/Ps carry a distinct identification code within the production identifier. The 2015 Edition Health Information Technology (Health IT) Certification Criteria Final Rule requires that the distinct identification code be parsed from the UDI when a medical device contains an HCT/P.

These requirements have the potential to significantly improve the traceability of medical devices containing HCT/Ps following distribution from the tissue processor. In addition, improvements in the ability of the supply chain to capture donor related identifiers could help to improve biovigilance and support outcome evaluation. However, the stakeholders involved in handling these particular products need to work together to gain the greatest leverage from the UDI regulation.

How does this topic impact the successful implementation and/or use of UDIs?

The activity will help to educate the UDI community about:

- The unique characteristics of HCT/Ps that necessitate that they be managed differently than other medical devices;
- The need for traceability between donor and recipient as an essential tracking requirement for HCT/Ps in order to support rapid donor specific product recall on a national and international basis;
- The role of internationally standardized product codes for HCT/Ps and their importance in biovigilance;
- The need to ensure harmonization of track and trace across all HCT/P products whether regulated as medical devices or biologics;
- The role of the distinct identification code production identifier that is specifically required for devices containing HCT/P; and,
- The need for the distinct identification code to be parsed from the UDI in order to meet 2015 edition Health IT certification criteria.

AFFECTED STAKEHOLDERS:

- Tissue Processors
- Distributors of medical devices containing HCT/P
- Hospital and dental office staff responsible for tissue/medical device management
- Hospital supply chain and clinical systems developers
- Hospital tissue management system developers
- Hospital and dental clinical systems developers
- Quality/Risk Management staff

REQUIRED STAKEHOLDERS:

- Tissue processors
- Hospital staff responsible for tissue/medical device management
- Dental office staff responsible for tissue/medical device management
- ERP
- Distributors
- Clinical Systems staff
- EHR vendors
- All UDI Issuing Agencies
- and FDA representatives

DELIVERABLES:

- GUIDANCE Document for healthcare providers/supply chain staff and labelers
- BUSINESS CASE/VALUE Summary
- TOOLS – Study Guide
- EDUCATION – webinar, PowerPoint presentation

COMMUNICATION PLAN:

TBD