How we work

Compounded Preparation Monograph Development Process

**Public health need**
- Medications to address vulnerable populations like pediatric or geriatric
- Medication elements that cannot be used due to allergies
- Medications that are not commercially available
- Medications to address drug shortages
- Medications for orphan disease states

**Stakeholders**
- Academia
- Industry
- Regulatory Authorities
- Compounding Member Support Organizations

**Constant Communication**

**Proposed monograph**

**Collection of data**

**Monograph draft and USP Expert Committee approval**

**Monograph proposed**
- Pharmacopeial Forum (PF) for public comments

**Monograph approved**
- by Expert Committees and published in the USP–NF

**Request for revision**
- A review request can be initiated by either USP or stakeholders for any monograph published in the USP–NF

* Monograph candidates have to meet USP’s criteria for inclusion in USP–NF (criteria include public health need, analytical data, approved legal status, and no known safety concerns, among others.)