**The Purchasing Experience**

The Packaging Accelerated Timeline Help (PATH) True-Validated packaging solution is a digital asset; it is IP in the form of a data set that integrates seamlessly into any Quality Management System (software or paper-based) and represents the digital transformation of medical packaging. As such, the possession of this digital asset in any form, must be closely monitored and usage is strictly limited to the legally licensed purchaser. Eagle Medical Packaging, Sterilization, Inc. (EMPS) will provide initial review of the data set in a format that restricts printing, digital capture, sharing, alteration, and generally discourages the unlawful dissemination of the document set. Upon completion of purchase all restrictions are removed. However, the only permissible dissemination of the document set is inclusion in your FDA submission(s), within the confines of your primary corporate entity, not including subsidiaries, affiliates, agents, or assigns; any other usage is prohibited, and unauthorized reproduction, possession, or dissemination will be prosecuted to the fullest extent allowed by law.

**IP Escrow**

Intellectual Property Escrow service providers facilitate the transfer of high-value digital assets by acting as an intermediary through which the IP, and the funds for purchasing the IP are funneled. Both the funds and the IP are held in escrow while final signatures are gathered. The release of funds and IP happens simultaneously once both parties agree that all prerequisites have been satisfied. The process to consummate the transfer is lengthy, but these controls are in place to protect both the buyer and the seller. Here is the workflow:

* Medical Device Original Equipment Manufacturer (OEM) creates account on the Eagle Medical (EMPS) web portal
* OEM digitally signs ‘readiness checklist’ to gain access to downloadables
  + The readiness checklist protects the OEM’s investment by confirming critical benchmarks, AND
  + Necessary data and deliverables to EMPS are immediately available
* OEM downloads eBook #3, Mutual NDA, and PATH contract
* EMPS/OEM sign mutual NDA
* OEM uploads critical info such as their top-level assembly drawing (released data only) for evaluation
* EMPS evaluates drawing and verifies that PATH is a viable solution for the specific medical device configuration
* EMPS sends quote for PATH routine production to 10K units/yr. pricing, along with credit terms
* OEM submits $5K nonrefundable deposit, which is fully creditable to PATH or custom development project
* OEM downloads LockLizard; allowing 24-hour access to restricted doc set to verify contents
* OEM provided with FDA Master File number; allowed time to verify MF on fda.gov
* OEM and EMPS formalize and sign the PATH contract
* OEM and EMPS sign the IP Escrow contract
* EMPS uploads document set to the Escrow portal with specified security controls
* OEM transfers payment balance to Escrow
* Escrow agent verifies receipt of both IP and funds
* OEM given short term, unrestricted access to the document set to verify contents and accessibility
* OEM and EMPS mutually green-light the transaction via secure conference call with escrow agent
* Escrow agent releases funds and IP to respective parties
* Onus on OEM to complete engineering rationale for adoption with support from EMPS

**Document Set Table of Contents**

PATH package validation protocol/Report

PATH system sampling plan

HFE package functionality and aseptic presentation

Access to FDA Master File for Sealing process, packaging design (material specifications, biocompatibility)

PATH pouch packaging assembly drawing

Generic Proxy Product top level assembly drawing

PATH 4-UP assembly drawing inner shipper

PATH labeling template (pouch, box, patient record)

PATH product box material specification

Transition Tyvek technical reference guide 2020

PATH 4-up shipper box material specification

PATH incoming inspection and set up procedure template

PATH peel pouch packaging procedure

PATH secondary packaging procedure

PATH sterile load configuration

E-submitter user manual