



**SEABROOK**  
TECHNOLOGY GROUP

# GxP COMPLIANT eDHR SOLUTION

FOR MEDICAL DEVICE, DIAGNOSTICS, AND BIOTECH MANUFACTURERS.

*powered by Tulip*

MAKE BETTER & FASTER OPERATIONAL & QUALITY DECISIONS.

ITERATIVE • RAPIDLY IMPLEMENTED • LOW RISK  
PROVIDES IMMEDIATE VALUE

The Seabrook GxP Compliant eDHR solution

**delivers value in weeks,**

is **easy to configure,**

**easy to deploy, &**

**continuously improves**

as capabilities are added.



[www.seabrookglobal.com](http://www.seabrookglobal.com)



Seabrook Technology Group



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# MEDICAL DEVICE, DIAGNOSTICS, & BIOTECH MANUFACTURERS CAN NOW:

- **ACHIEVE OPERATIONAL EXCELLENCE THROUGH REAL-TIME DATA COLLECTION.**
- **ENSURE QUALITY WITH GXP COMPLIANCE.**
- **GAIN TIMELY RETURN ON INVESTMENT THROUGH RAPID IMPLEMENTATION.**

## THE CHALLENGE

The challenge for many manufacturers (especially those considered to be “small to medium”) in regulated industries is to think beyond the use of paper and to move toward digital transformation.

However, questions of scope and cost become immediate roadblocks to the first steps of this journey. Manufacturers may abandon the idea of a digital solution, believing that there is not a solution that can be implemented quickly and lead to a timely return on investment. Although most manufacturers agree that paper is far from perfect and brings significant risk, many are not able to justify the cost and interruption that may be associated with traditional solutions.

## THE OPPORTUNITY

The real opportunity today is that improvement of the entire manufacturing process is possible through a variety of solutions, and these solutions can be utilized by medical device manufacturers of varied sizes.

### What is an eDHR?

An eDHR (Electronic Device History Record) is a paperless, electronic solution that can capture information, enforce accurate production, and provide the visibility needed to produce high-quality products with dramatic increases in productivity. Now more than ever, the implementation of an eDHR can be completed quickly, utilizing a cost-friendly method, and with a timely ROI.

## THE SOLUTION

For Product Owners or Manufacturing and Quality Assurance Leaders & Manufacturing Engineers who need to digitalize their manufacturing process to make better & faster operational & quality decisions, the **Seabrook GxP Compliant eDHR solution** is the only iterative, low risk, digital data collection approach that provides immediate value through rapid implementation.

Unlike traditional MES solutions that deliver substantial value to a company but take some time to realize, **the Seabrook GxP Compliant eDHR solution delivers value in weeks, is easy to configure, easy to deploy, & continuously improves as capabilities are added.**



# THE SEABROOK GXP COMPLIANT EDHR:

- is a ready-to-use hosted SaaS eDHR, which is GxP Compliant
- provides immediate value through rapid implementation (delivers value in weeks)
- is easy to configure, easy to deploy, & continuously improves as capabilities are added.
- fully complies with FDA Title 21 CFR Part 11
- includes role, meaning, signature, and verification method
- facilitates robust security access and computer-generated audit trails
- enables data retention and archiving, unique username/password enforcement and signature event capture



## FUNCTIONALITIES OVERVIEW

### Data Collection

- Data Collection Definitions
- Manual Data Collection

### eDHR Viewer

- Simple and Flexible

### Security and Access

- Role-Based Access Control
- Access Permissions

### Order Tracking

- Production Visibility

### Quality Enforcement

- Material Issue Enforcement
- Route Enforcement
- Task Completion Enforcement

### Process Time Enforcement

- Dynamic Timers
- Record Production Event
- Execute Business Rule

### Electronic Procedures

- Provides Guided Set of Tasks
- “One Stop Shop” for Operator
- Task Sequence/Prerequisite Tasks

### Electronic Signature

- 21 CFR Part 11 Compliant
- Includes Role, Meaning, Signature Count, Verification Method
- User/Password Authentication

### Resource Audit Trail

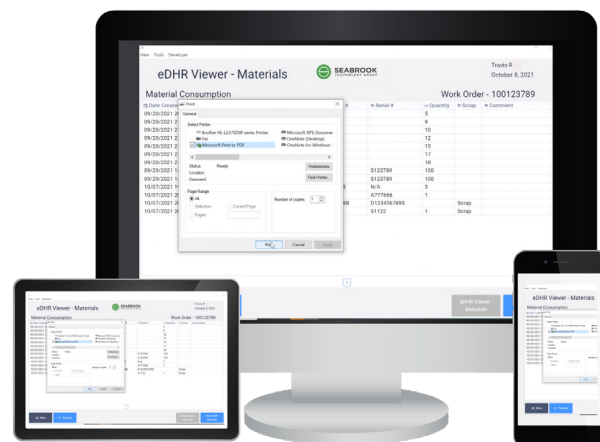
- Complete Resource Activity Traceability
- “As-Built” History

### Manufacturing Audit Trail

- Complete Production Activity Traceability
- “As-Built” History

### Print-Ready eDHR

- Digital-PDF Creation
- Physical - Paper Printing



Seabrook's GxP Compliant eDHR Solution is powered by Tulip.

[www.tulip.co](http://www.tulip.co)



**TULIP**



# SEABROOK

TECHNOLOGY GROUP

## WE ARE MANUFACTURING TECHNOLOGY EXPERTS.

At Seabrook Technology Group, our focus is to provide Connected Manufacturing Solutions to Medical Device, Diagnostic, and Biotech Manufacturers

- Offices in the US, UK, Ireland, India, and the Philippines
- Official Siemens Reseller – Siemens Solution (Smart) Partner
- Tulip Manufacturing App Partner
- AWS Consulting Partner
- Team of Industry-Known Connected Manufacturing Experts
  - ISO 9001 Certified
  - Siemens Certified Consultants
  - MESA Certified Consultants
  - CPIM Certified Consultants
  - PMP Certified Consultants
  - Integration, Manufacturing Intelligence, and DHR Requirements Expertise

### For more information:

#### The Americas

600 Corporation Drive,  
Suite # 108,  
Pendleton, Indiana 46064  
Tel: +1 317 426 0699  
sales@seabrookglobal.com

#### India

House No. 552 E,  
Vinayaka, HBCS Layout,  
Nagarbhavi, Bengalura,  
India 560072  
sales@seabrookglobal.com

#### Ireland

Cork Business & Technology Park  
Cork Ireland  
Tel: +353 21 4800 840  
sales@seabrookglobal.com

#### Philippines

Unit 201-202 Costa Grande Bldg,  
Barangay Palico 1,  
Imus City, Cavite  
Philippines  
sales@seabrookglobal.com

#### UK

Seabrook Technology UK Ltd  
58 Pen Y Bryn  
Wrexham, LL13 7HY  
United Kingdom  
+44 (800) 3688588  
sales@seabrookglobal.com

[www.seabrookglobal.com](http://www.seabrookglobal.com)