

# PARTNERSHIPS COMMITTED TO BETTER QUALITY TRIALS

HCL: Agile. Innovative. Efficient.



## HCL AMPLIFIED R&D DELIVERIES: REGULATORY SERVICES SYNOPSIS

REACHING CLIENTS WITH A WIDE-RANGING MODEL OF REGULATORY SOLUTIONS THAT ENHANCES PERFORMANCE AND EXCELLENCE

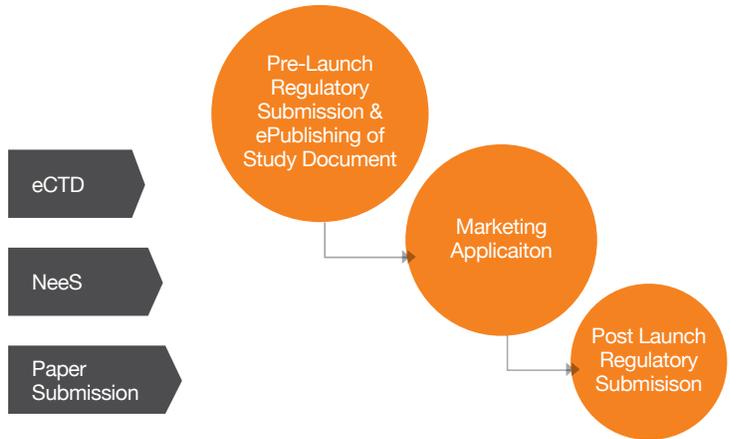
Regulatory organizations in Life Sciences are facing unique business challenges. More tough, global authority's requirements have created varied and complex opportunities for initial filings, lifecycle management and ongoing compliance.

There is a challenge to maintain authorization for a full portfolio of commercially available drugs, while continuing to innovate and progress new investigational compounds. Regulatory organizations are confronted with the challenge of supporting expansion to new patients and geographies, market desire for distinguished treatments and a simultaneous mandate to find more effective and efficient ways to operate. Meeting these mandates strains current capacity and diverts precious resources from the desired work focus: bringing differentiated new products to patients.

HCL offers a comprehensive delivery model of regulatory service options and solutions, designed to help regulatory organizations relieve capacity constraints, secure authorization and sustain global compliance. Our regulatory clients will realize improvements in submission ready deliverables, reduced cost of submission and ongoing maintenance, and streamlined offshore operations.

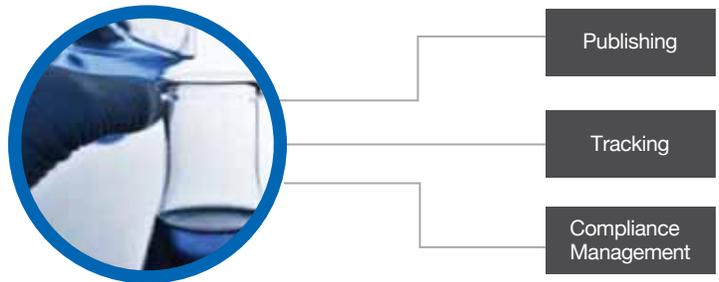
# HCL EFFICIENT DELIVERY OFFERINGS FOR CLIENTS ACROSS THE GLOBE

**HCL REGULATORY ASSISTANCE:** Our strategic regulatory services provide focused solutions to help our clients enhance their Regulatory Affairs effectiveness and compliance. HCL has the ability to operate as an extension of our sponsors' regulatory group. We provide a holistic submission capability which can be utilized to deliver submissions by type (across the full product lifecycle) and/or by geographic area by using preferred technology platforms.



## PUBLISHING INSIGHT:

Our enabling technologies help clients in the areas of publishing (Paper, eCTD & NeeS), tracking and Compliance measurement and management. HCL's Technology provides comprehensive process management controls. It connects processes, automates tasks and provides the underpinning of crossfunctional efficiency. Above all, HCL being a technology company with proven record with numerous clients around the globe is capable of operational executions on any given platform.



## SPL Conversion and Electronic Submission

- Convert the drug product labels into XML format
- Place the XML-formatted information into the compliant SPL structure
- Ensure Compliance to regulatory authorities specifications
- Check the presence and format of data values
- Ensure that your SPL is FDA submission ready
- Validate and Ensure that the SPL is region submission ready
- Submit SPL on your behalf via our Electronic Submissions Gateway (ESG) services

“Our association with HCL takes Glenmark’s clinical practice to the next level as we cater to global consumers that have a very specific interest. Glenmark has chosen HCL’s easy Labeling Solution because it promises to complement our efforts to improve management of the product information lifecycle”.

# LABEL MANAGEMENT

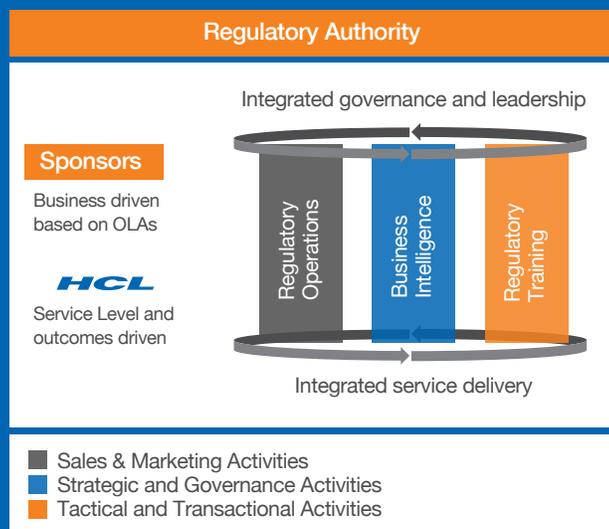
HCL has capabilities to create labels in Structured Product Labeling (SPL) format as Defined by US FDA. By doing so, our aim is to make SPL document exchangeable without the need for additional transformation steps. We also have the capability of converting SPL document into PLR (Physician Labeling Rule) format. Every SPL output is validated against ELIPS guidelines

## eTMF SERVICES

For organizations that are moving from manual paper handling processes to electronic processes, HCL delivers a broad set of features that automate a range of clinical trial document and medical image acquisition and management processes. For security, redundancy and backup, the HCL platform is offered with dedicated secure server resources for each study. The HCL platform is the only eTMF solution with integrated multi-organization digital signing, allowing investigators, sponsors, CROs and stakeholders to digitally sign documents anytime, anywhere from inside the application globally.



## AROUND THE GLOBE COMMUNICATION APPROACH



### Benefits of the Proposed Regulatory Operating Model

- **Partnership** – By establishing a combined team, formal governance model and shared objectives HCL will act as your partner and demonstrate our commitment to Authority
- **People Development** – Client will continue to own the strategy and drive the business
- **Right-sized Team and Flexible Model to Variable Cost-** Ability to ramp up or down based on Client’s business demand
- **Reduction in Operating Costs** – Leverage HCL’s world class Offshore/Onshore Networks to lower Client’s total cost to deliver operational services
- **Translate synergies into savings** - With this model, HCL would be primarily responsibility for your Regulatory Operations and Submission Support. You should expect and we will commit to saving and synergies
- **Continuous Improvement** - A commitment to do ‘more with less’ and ‘creating more output’ and overall process improvement

## WHAT OUR CLIENTS TALK ABOUT US

An agreement with Glenmark Pharmaceuticals Ltd. to implement HCL’s comprehensive drug labeling framework — easy Labeling Solution. Developed specifically for pharmaceutical companies, HCL’s easy Labeling Solution assisted Glenmark to streamline drug labeling, manage product information lifecycles and comply with the U.S. FDA’s Structured Product Labeling (SPL) regulations.

# THE WORLD IS NOTICING SOMETHING UNIQUE ABOUT HCL

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HCL's Employees First is a new and radical management philosophy which will catch on with the world sooner or later



HCL's Employees First and 'democratization' of management concept could 'bring about a corporate renaissance'



Harvard Business School teaches about HCL as a case study on business transformation highlighting the Employees First initiative



Darden School of Business has done a case study on the impact created by HCL through its "Employees First Customers Second" practice



Best Employer in India – Hewitt Study 2009



Ranked as the world's Most Innovative Company for its workforce practices



One of Britain's Top Employers for the 4th Consecutive Year



WorldBlu lists HCL as one of the 44 Most Democratic Workplaces in the World



Employees First, Customers Second is now a book published by Harvard Press. Admired by many global thought leaders -Tom Peters, Tony Hsieh, Gary Hamel, JudyMcGrath, Ram Charan, Victor K. Fung



Exclusive report on EFCS recognizes that this philosophy empowers HCL's frontline employees to make decisions and take actions for the benefit of customers

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

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*Relationship*<sup>™</sup>  
BEYOND THE CONTRACT

**HCL**