



HCL Amplified R&D Deliveries:

REGULATORY SERVICES SYNOPSIS

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

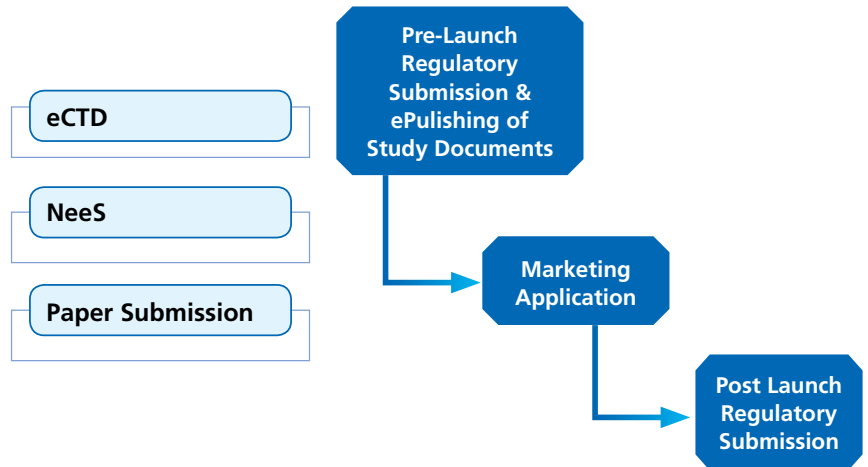
Regulatory organizations in Life Sciences are facing unique business challenges. More tough, global authority's requirements have created varied and complex opportunities for initial filings, lifecycle management and ongoing compliance.

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.

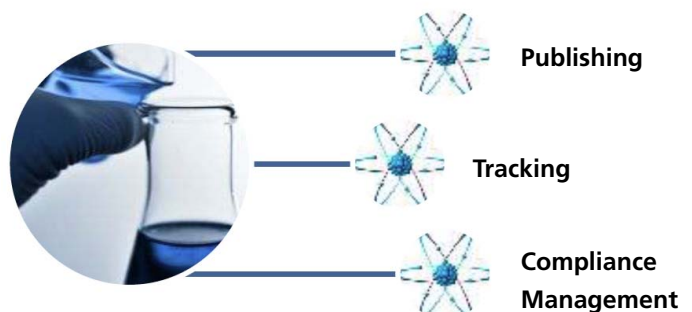
HCL EFFICIENT DELIVERY OFFERINGS FOR CLIENTS ACROSS THE GLOBE

HCL Regulatory Assistances 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.



LABEL MANAGEMENT

HCL has capabilities to create labels in Structured Product Labeling 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.

WHAT OUR CLIENTS TALK ABOUT US

An agreement with Glenmark Pharmaceuticals Ltd. to implement HCL's comprehensive drug labeling framework — easy Labeling Solution.

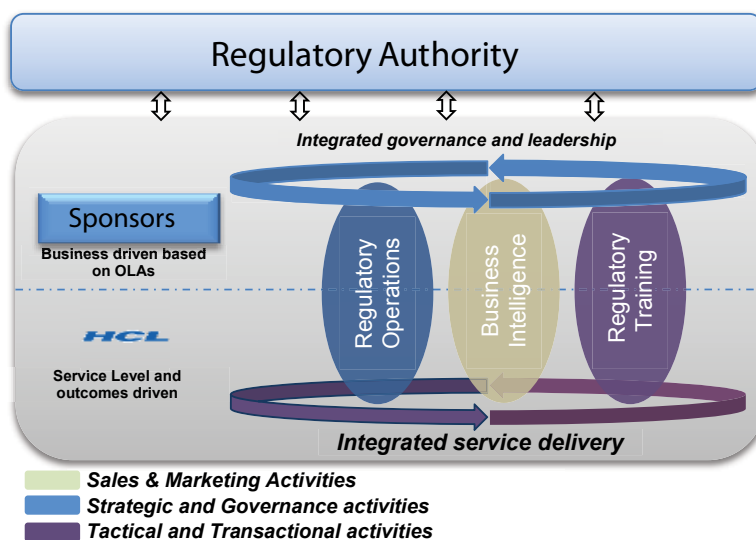
Developed specifically for pharmaceutical companies, HCL's easy Labeling Solution assisted Glenmark to streamline drug labeling, manage product information lifecycles and comply with the U.S. FDA's Structured Product Labeling (SPL) regulations.

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
- Ensuring 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 its efforts to improve management of the product information lifecycle".

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 saving** - 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

THE WORLD IS NOTICING SOMETHING UNIQUE ABOUT HCL



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 Asia and in India – Hewitt Study 2008



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, Judy McGrath, 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



IT IS EMPLOYEES FIRST

The 'Employees First' philosophy at HCL, the first such articulation in the IT industry, is at the core of our efforts to provide our employees with a work environment and culture that they can take pride in.

About HCL Technologies

HCL Technologies is a leading global IT services company, working with clients in the areas that impact and redefine the core of their businesses. Since its inception into the global landscape after its IPO in 1999, HCL focuses on 'transformational outsourcing', underlined by innovation and value creation, and offers integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and BPO. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multi-service delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers our 85,194 transformers to create a real value for the customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of US\$ 4.4 billion (23,499 crores), as on 31st December 2012 (on LTM basis).

For more information, please visit www.hcltech.com

For more information contact healthcare@hcl.com



Hello, I'm from HCL! We work behind the scenes, helping our customers to shift paradigms and start revolutions. We use digital engineering to build superhuman capabilities. We make sure that the rate of progress far exceeds the price. And right now, 90,000 of us bright sparks are busy developing solutions for 500 customers in 31 countries across the world. How can I help you?

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