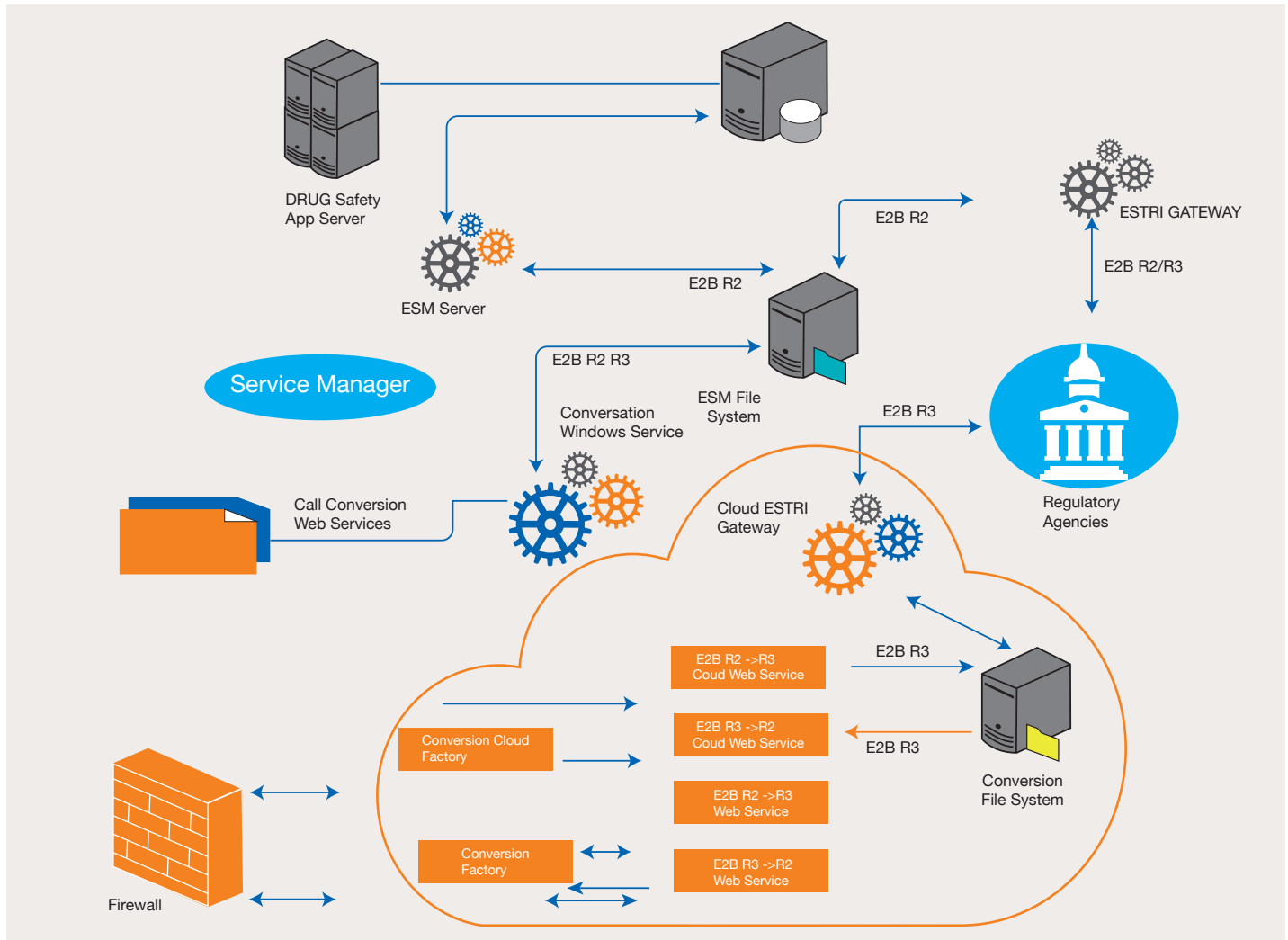


E2B R2 - R3
CONVERSION
UTILITY



Currently Marketing Authorization Holders (MAH) report adverse events in E2B(R2) specification. The International Conference on Harmonization (ICH), in collaboration with the Standards Development Organizations (SDOs) has developed E2B(R3) to enable wider inter-operability across the regulatory and healthcare communities. None of the current drug safety systems (ARISg, Argus or Bespoke) are E2B(R3) compliant. With the need to comply with the specification, MAH will have to upgrade their safety systems.

HCL offers a comprehensive E2B R2 - R3 conversion utility. The utility enables safety system's Electronic Submission Module (ESM) to comply with E2B(R3) specification. The utility receives E2B(R2) ICSR and acknowledgement files generated by the safety system and converts them to E2B(R3) specification. The converted files are placed into ESTR1 gateway file systems to be transmitted to various reporting destinations. The utility also converts E2B(R3) files to E2B(R2), which can be imported into the safety system.



PRODUCT FEATURES

- ❑ The E2B utility is drug safety system agnostic. The utility has two modules
- ❑ Service Manager is installed and configured on the ESM file system server. The service manager will pool E2B(R2) files from the configured ESM Export folder, call the conversion web service and place the converted E2B(R3) file to the ESTR1 gateway file system to be transmitted to the intended reporting destination.
- ❑ Conversion Web Service can be either hosted on premises or can access HCL hosted services on Amazon Web Service (AWS) with multi tenancy capabilities. The web services are stateless and the data transmitted are not persisted at any point of time ensuring data privacy.
- ❑ Original E2B files are archived to a specified folder for future reference.
- ❑ The utility can be configured to convert Extended E2B (E2B+) R2 files, capturing additional E2B(R3) specific fields, enabling non E2B(R3) complaint safety system to be fully E2B(R3) compliant.



The screenshot shows a Windows-style application window titled "Service Manager". It contains a configuration form with the following fields and values:

Field	Value
Enterprise ID	10000
Enterprise Name	HCL
Windows Service Frequency (in minutes)	1
Web Service IP Address	e2bconversionutilit-erv.elasticbeanstalk.com
ESM Export Folder	d:\test\data\esmexport
ESM Import Folder	d:\test\data\esmimport
ESTRI Export Folder	d:\test\data\estriexport
ESTRI Import Folder	d:\test\data\estriimport
Enable Cloud Distribution	<input type="checkbox"/>
Log Folder	d:\test\log
Archive Folder	d:\test\data\archive

A "Create" button is located in the top right corner of the form area.

HCL E2B SUBMISSION ON THE CLOUD

HCL offers a complete E2B submission on the cloud, based on subscription model. The subscription policy can be either for the transmission of E2B(R2) or E2B(R3). HCL hosted ESTR1 Gateway will enable end to end ICSR/ACK file transmission.

- ❑ E2B R2->R3 Cloud Web service will convert ICSR and Acknowledgement export files from E2B R2 to R3 specification. Upgrade conversion style sheet (XSL) files will be developed for the conversion. The converted files will be placed into the HCL Cloud ESTR1 Gateway 'Out' folder to be transmitted to the intended reporting destination
- ❑ E2B R3->R2 Cloud Web service will spool from HCL Cloud ESTR1 Gateway 'In' folder for importing ICSR and acknowledgement files and convert ICSR and Acknowledgement import files from E2B R3 to R2 specification. The converted files can be accessed by calling a web service which will return universally unique identifier (UUID) URLs for each of the xml files to be imported into the safety system.

BUSINESS BENEFITS

- Major regulatory bodies are still finalizing their respective business processes and rules to formalize E2B R3 Specification. Each one of them have different timelines and it would need multiple upgrades to the safety system. HCL's solution can help avoid multiple upgrades to the current safety system until major regulatory bodies formalize R3 compatibility.
- Multi tenanted service hosted on AWS cloud, fully managed and maintained by HCL. The hosted service will not only convert E2B R2 to R3, but will also have Electronic Standards for the Transfer of Regulatory Information (ESTRI) Gateway implemented for submission to various Authorities ensuring End-to-End Cloud based solution.
- The solution can also be implemented on premises. The lightweight deployment needs a basic server to run.



HCL LIFE SCIENCES & HEALTHCARE

HCL is a leading provider of Life Sciences and Healthcare Business and Technology services. We are the chosen service provider for enabling new growth drivers for our clients, providing them with industry leading best practices, taking care of their compliance needs and ensuring goldstandard process cycle times. Our clientele includes seven of the top ten global pharmaceutical companies, seven of the top ten medical devices companies, six of the top ten health plans, three of the top five CRO's and two of the top three data providers. Equipped with certified technology experts and domain specialists, HCL offers services in critical areas of the life sciences and healthcare eco system such as drug discovery, clinical development, drug safety, regulatory compliance, manufacturing and plant automation, commercial, Healthcare analytics, Population Health Management [PHM], mHealth, member experience management [MEM], fraud, waste and abuse management [FWA].

Let's connect:



Please feel free to write to us at contact.lsh@hcl.com

ABOUT HCL

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 emergence on the global landscape, and after its IPO in 1999, HCL has focused on 'transformational outsourcing', underlined by innovation and value creation, offering an integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and business services. 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 Life Sciences & Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers its 105,000 transformers to create real value for customers.

HCL Technologies, along with its subsidiaries, had consolidated revenues of US\$ 5.8 billion, for the Financial Year ended as on 31st March 2015 (on LTM basis). For more information, please visit www.hcltech.com

ABOUT HCL ENTERPRISE

HCL is a \$6.5 billion leading global technology and IT enterprise comprising two companies listed in India – HCL Technologies and HCL Infosystems. Founded in 1976, HCL is one of India's original IT garage start-ups. A pioneer of modern computing, HCL is a global transformational enterprise today. Its range of offerings includes product engineering, custom & package applications, BPO, IT infrastructure services, IT hardware, systems integration, and distribution of information and communications technology (ICT) products across a wide range of focused industry verticals. The HCL team consists of over 100,000 professionals of diverse nationalities, who operate from 31 countries including over 505 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms. For more information, please visit www.hcl.com

NOTES

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