IBM Solution for Compliance in a Regulated Environment V6.1 addresses compliance and regulated document management requirements across multiple industries and applications.

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Overview

IBM® Solution for Compliance in a Regulated Environment (IBM SCORE) V6.1 adds:

- Support for latest Electronic Common Technical Document (eCTD) regulatory submission specifications in the European Union (EU 1.3). With these additions, IBM SCORE now supports all current regulatory submission specifications for the United States, Canada, and European Union. Additional enhancements made based on customer eCTD submissions and usage.
- Ability to create dynamic folder views providing increased visibility to content.
- Support for copying simple documents.
- Support for document review cycles including annotations support for annotating documents using Adobe® reader.
- Enhanced flexibility to configure and display search results.
- User interface enhancements including actionable icons and better support for displaying multi-value attributes.
- Upgrade of IBM SCORE component stack provides streamlined installation and enhancements in performance and scalability.

Key prerequisites

Refer to the Technical information section for details.

Planned availability dates

March 27, 2009: Electronic software delivery

April 17, 2009: Media and documentation

Availability of programs with encryption algorithm in France is subject to French government approval.

Cryptography in this product is limited to password encryption, authentication, or digital signature.

Description
IBM Solution for Compliance in a Regulated Environment (SCORE) V6.1 provides integrated
document lifecycle management and Electronic Common Technical Document (eCTD) lifecycle
management, enabling submission preparation to begin earlier than with traditional systems.
This can help significantly reduce the work that must be done during the final steps in preparing
a submission. The submissions management capabilities include planning, tracking, monitoring,
and status dashboards. Review and approval workflows are supported at the eCTD and the
node level. The Auto-Suggest feature helps dramatically reduce the effort and time needed to
assemble an eCTD because you can suggest placement of documents within an eCTD based
on a document's metadata. A single audit log is used to track activities from document creation
through eCTD submission, helping to support regulatory compliance efforts.

IBM SCORE V6.1 allows cross references to be added earlier in the process, from document
creation, review, and assembly, and they are maintained as a document goes through multiple
versions. This can help dramatically reduce the time and effort needed to maintain cross
references, and eliminate the rush to add large numbers of cross references during the final
assembly of a submission. IBM SCORE can also improve accuracy, as users can check cross
references during the creation, review, and approval phases of documents and submissions.
IBM SCORE provides cross reference tools for Microsoft® Word and Adobe Acrobat.

IBM SCORE also enables the tracking of communications and correspondence with regulatory
agencies, and the creation, review, and approval of responses to inquiries. It provides service
oriented architecture (SOA) support by including Web Services interfaces to ease integration
with business processes and other applications such as ERP, CRM, and paper publishing
applications.

For life sciences companies, such as pharmaceutical, biotech, generics manufacturers, contract
research organizations, and contract manufacturing organizations, IBM SCORE provides a
foundation to support efforts to comply with regulations from the FDA such as 21CFR11 and
GxPs.

IBM SCORE is for regulated business processes including research and development, clinical
trials, regulatory affairs and submissions, manufacturing, corrective action and preventative
action, safety and adverse event reporting, packaging and labeling, marketing materials and
advertising.

IBM SCORE can also be used in less regulated areas of the organization such as research
and discovery, good IT practices (GITP) documentation, IP management, contracts, and legal.
Because of IBM SCORE's extensive configuration options, it provides a solution for document
management needs across a variety of industries and departments.

IBM SCORE is offered at an attractive, Authorized User price. You may currently suffer from
an overly complex buying experience where you must buy from multiple software vendors with
different pricing models. IBM SCORE is designed to offer the software functionality you want in a
single, simpler package.

Consulting, implementation, validation, and training services are available from IBM Global
Business Solutions and can deliver validated, production-ready systems. IBM's experience and
project accelerators speed time to value for the user community.

Note: Although IBM SCORE enables organizations to address compliance and regulated
document management requirements, it is your responsibility to comply with regulatory agencies' regulations and directives.

<table>
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<tr>
<th>Program number</th>
<th>VRM</th>
<th>Program name</th>
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<tr>
<td>5724-K83</td>
<td>6.1.0</td>
<td>IBM Solution for Compliance in a Regulated Environment</td>
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Offering Information

Product information is available via the Offering Information Web site

http://www.ibm.com/common/ssi

Also, visit the Passport Advantage® Web site

http://www.ibm.com/software/passportadvantage

Publications

No hardcopy publications are shipped with this product.

The IBM Publications Center

http://www.ibm.com/shop/publications/order

The Publications Center is a worldwide central repository for IBM product publications and marketing material with a catalog of 70,000 items. Extensive search facilities are provided. Payment options for orders are via credit card (in the U.S.) or customer number for 20 countries. A large number of publications are available online in various file formats, and they can all be downloaded by all countries.

Technical information

Specified operating environment

Hardware requirements

The exact configuration you need to support your environment, with satisfactory response time, will vary depending on the size of the objects you are working with. Individual display response times vary depending on workstation speed, memory, size of objects, and network and server workload. You should consult your IBM representative to determine the recommended hardware configurations and software requirements for your utilization of the IBM SCORE solution.

Software requirements

IBM SCORE includes several IBM software products as defined in the packaging section but requires certain third-party (or vendor) products from ISI, Adobe, and Documentum depending on the configuration that is implemented. IBM SCORE can be installed with either IBM Content Manager or Documentum Content Server as the repository but not both at the same time.

The program’s specifications and specified operating environment information may be found in documentation accompanying the program, if available, such as a README file, or other information published by IBM, such as an announcement letter. Documentation and other program content may be supplied only in the English language.

Planning information

Packaging

IBM SCORE V6.1 now uses the following components and includes them in the IBM SCORE package for usage with IBM SCORE:

- IBM Content Manager V8.4.1
- IBM DB2® Enterprise Server Edition V9.1
- IBM Tivoli® Directory Server V6.1
- IBM WebSphere® Application Server Network Deployment V6.1
- IBM WebSphere Portal Server V6.1
Security, auditability, and control

Solution for Compliance in Regulated Environments uses the security and auditability features of the host hardware or software.

The customer is responsible for evaluation, selection, and implementation of security features, administrative procedures, and appropriate controls in application systems and communication facilities.

Global Technology Services

Contact your IBM representative for the list of selected services available in your country, either as standard or customized offerings for the efficient installation, implementation, or integration of this product.

Ordering information

For ordering information, consult your IBM representative or authorized IBM Business Partner, or visit http://www-306.ibm.com/software/support/pa.html

This product is only available via Passport Advantage. It is not available as shrinkwrap.

Product information

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<td>Content Manager</td>
<td>Solution for Compliance in a Regulated Environment</td>
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Program name

IBM Solution for Compliance in a Regulated Environment

PID number 5724-K83

Authorized Users

Charge metrics definitions

Authorized User

IBM SCORE is sold per Authorized User in minimum groups of 50.

An Authorized User entitlement must be obtained for each individual user, with a specific identity, accessing the program in any manner. Each Authorized User entitlement is attributable to one and only one unique individual specified user, either within or outside your enterprise. An Authorized User entitlement is required for each specifically identified individual user who accesses the program or any component, application, feature, function, or capability thereof, either directly or indirectly, through any means on behalf of the user. Authorized Users require entitlements for accessing content managed within, or distributed from, the program. Each Authorized User entitlement entitles one unique individual user to establish one or more connections to any number of program instances across any of the supported platforms. An Authorized User entitlement may only be reassigned for the long-term replacement of personnel. The programs may be installed on one or more computers, and accessed by multiple users, provided that an Authorized User entitlement has been obtained for each unique individual user.
## Passport Advantage program licenses

### Solution for Compliance in Regulated Environment

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### Passport Advantage customer: Media pack entitlement details

Customers with active maintenance or subscription for the products listed are entitled to receive the corresponding media pack.

#### IBM SCORE V6.1.0

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## Terms and conditions

The information provided in this announcement letter is for reference and convenience purposes only. The terms and conditions that govern any transaction with IBM are contained in the applicable contract documents such as the IBM International Program License Agreement, IBM International Passport Advantage Agreement, and the IBM Agreement for Acquisition of Software Maintenance.

### Licensing

IBM International Program License Agreement including the License Information document and Proof of Entitlement (PoE) govern your use of the Program. PoEs are required for all authorized use.

Part number products only, offered outside of Passport Advantage, where applicable, are license only and do not include Software Maintenance.

### License Information form numbers

<table>
<thead>
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<td>Solution for Compliance in Regulated Environment</td>
<td>5724-K83</td>
<td>L-GFUR-7K3NN6</td>
</tr>
</tbody>
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The program's License Information will be available for review on the IBM Software License Agreement Web site

Limited warranty applies
Yes

Money-back guarantee
If for any reason you are dissatisfied with the program and you are the original licensee, you may obtain a refund of the amount you paid for it, if within 30 days of your invoice date you return the program and its PoE to the party from whom you obtained it. If you downloaded the program, you may contact the party from whom you acquired it for instructions on how to obtain the refund.

For programs acquired under the IBM International Passport Advantage Agreement, this term applies only to your first acquisition of the program.

Authorization for use on home/portable computer
The program may be stored on the primary machine and another machine, provided that the program is not in active use on both machines at the same time. You may not copy and use this program on another computer without paying additional license fees.

Solution for Compliance in Regulated Environment: No

International Passport Agreement

Volume orders (IVO)
No

Passport Advantage applies
Yes, and through the Passport Advantage Web site at

http://www.ibm.com/software/passportadvantage

This product is only available via Passport Advantage. It is not available as shrinkwrap.

Other terms

IBM Operational Support Services - SoftwareXcel
No

System i Software Maintenance applies
No

Educational allowance available
Education allowance does not apply.

Education software allowance does not apply.

Special education prices are available for qualified customers through Passport Advantage.

Prices

For additional information and current prices, contact your local IBM representative.

Passport Advantage

For Passport Advantage information and charges, contact your IBM representative or authorized IBM Business Partner. Additional information is also available at
Business Partner information

If you are an IBM Business Partner -- Distributor for Workstation Software acquiring products from IBM, you may link to Passport Advantage Online for resellers where you can obtain Business Partner pricing information. An IBM ID and password are required.

https://www.ibm.com/software/howtobuy/passportadvantage/paoreseller/emea/channelannouncement

Announcement countries

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