

The Hollis Group, Inc.	Dept.	App.
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Subject:	R & D	
Infrastructure Assurance	Eng.	

SPRIITS™ / SpecScripton™
Standard Practices for Regulated
Infrastructure IT Systems
Document System Licensing Program

C3Q™, SPRIITS™, and SpecScripton™

FAQ – Frequently Asked Questions

C3Q™ is the Concurrent Computer Configuration and Qualification™ Methodology developed by The Hollis Group, Inc. C3Q™ includes all of the policies, procedures, methods, audits, etc., you need to demonstrate and document the confidentiality, integrity, and availability of: 1.) a computer and network infrastructure (CNI); 2.) the data, information, and records managed by the CNI; and 3.) the software-based application systems operating on the CNI.

SPRIITS™ (Standard Practices for Regulated Infrastructure IT Systems™) is the document set that instantiates the C3Q™ methodology. The 2004Q3 Release Set of SPRIITS™ includes 73 documents. These documents do not provide guidance on a high-level methodology. They provide a fully-reduced-to-practice set of SOPs, blank forms, work instructions, operational checklists, setup methods, test scripts, etc., that can be used as-is with no additional editing, to do your work.

SpecScripton™ is the document system licensing program.

Is this a System Development Life Cycle (SDLC) Methodology?

You could classify C3Q™ in the generic category of SDLCs, but to our knowledge it is the only methodology designed specifically for network qualification and for extending this network qualification into the application space. Since networks tend to have no planned end-of-life or decommissioning event, C3Q™ accommodates this ‘operate forever’ criterion, and is designed very differently than an SDLC that presumes all systems are eventually retired.

OK, what makes this design different?

C3Q™ consists of three tightly-integrated sections of standard practices:

- **Computer and Network Infrastructure Qualification (CNIQ)**
- **Dynamic Change and Document Management (DCDM)**
- **System Development and Deployment Methodology (SDDM)**

As a set, these standard practices cover pretty much everything you need to run an IT shop in a regulated industry.

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Just what exactly do we buy, anyway?

Since SPRIITS™ is intellectual property, you don't buy it in the traditional, literal sense. Instead, you purchase a license to use the document set. The documents are delivered on CD-ROM as editable word processing files.

Does that mean we only rent the document set?

No. The SpecScripton™ license includes a non-transferable, perpetual license for the purchaser to use the SPRIITS™ document set at the Site (or Sites) and for the number of Authorized Users specified at the time of purchase. You can use them at that location for as long as you stay in business.

What about extensions, revisions, and updates?

Various regulatory agencies require life sciences companies to update their documents periodically, and information technology turns over every 24 – 36 months. Because of these, Hollis assigns a two-year expiration date to each SPRIITS™ document. In other words, we update every document every two years. We issue quarterly releases.

The SpecScripton™ license includes an option to subscribe to these updates. Full-site, retail license agreements usually include the first year of document updates. None of these updates are mandatory, and not purchasing them does not encumber your license to continue to use the SPRIITS™ version you originally purchased.

What about training and deployment services?

Hollis has developed a complete training program for C3Q™ / SPRIITS™. We have recently partnered with PDA to deliver C3Q™ training through PDA-TRI and certification verification services through PDA-ARC. We are in the process of training a cadre of Certified Practitioners in the C3Q™ Methodology. Until we have a certified cadre of independent Practitioners in the field, Hollis will provide training and support services directly staffed by the SPRIITS™ developers.

Is C3Q™ / SPRIITS™ 21 CFR 11 Compliant?

The C3Q™ methodology does not have a one-to-one relationship with any specific set of regulations, and we strongly discourage our clients from allowing regulations to drive their infrastructure designs. This way, under HIPAA, EPA, OSHA, SEC, DEA, or any other regulation set, your **system** is structurally compliant. We recommend industry best practices, and proven, international standards, not regulation-driven compliance.

If you design for excellence rather than compliance, you won't have to change your strategy and re-invent the wheel every time any agency changes its interpretation of any given regulation. C3Q™ and SPRIITS™ have been designed this way and, when correctly

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implemented, will enable you to bring your computer and network infrastructure into compliance with **any** regulatory requirements.

Has C3Q™ been validated by the FDA?

NO! The FDA regulates, inspects, and licenses pharmaceutical, medical device, blood product, etc. research, manufacturing, and services products and facilities. The FDA does not have the authority or mission to inspect software methodology providers. In fact, several US federal regulations and laws prohibit the FDA from endorsing products or services. The Hollis Group, Inc.'s official position is that these policies, established by law and regulation, are prudent and we support them.

By way of note: If any company or person presents an "FDA endorsement" to you, it is false. We would recommend that you report this misinformation immediately to the FDA. Hollis would be glad to assist you, at no charge, in identifying the appropriate Compliance Safety Officer to whom you should make this report.

On the other hand, C3Q™ is being used at a plurality of sites that have been inspected by a plurality of regulatory agencies, sponsors, third-party auditors, and internal audit teams. To date, none of Hollis's customers that have passed a Hollis audit of their C3Q™ implementation (or one done by a C3Q™ Certified Practitioner) has received any significant observations, finding, or warnings. In fact, several have received unsolicited commendations for the quality of their verification, validation, qualification, and compliance.

Hollis can arrange for you to contact and / or visit specific reference accounts. Please see the next page if you'd like to know who has found SPRIITS™ / C3Q™ acceptable.

How do we evaluate SPRIITS™ / C3Q™?

This is the easiest part of the process. Contact us at the address below, and we'll forward a copy of our Product Evaluation Agreement to you. Execute this, promising that you're not going to "swipe" our intellectual property, and we'll send you a printed set of the documents for a 30-day review. We'll also forward some of our copyrighted training materials and lead you and your team through an overview of the C3Q™ Methodology, either on-site or via conference call.

Which Agencies and Companies have Approved SPRIITS™ / C3Q™?

NONE! As we said before, regulatory agencies are not in the business of approving or recommending methodologies. Generally, life sciences companies also refrain from such endorsements. However, agencies and sponsor companies do inspect and audit life sciences services vendors (CROs, contract packagers / manufacturers, etc.) for the compliance and competence of their IT operations.

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We are very proud to note that, for all of the organizations that have deployed SPRIITS™ / C3Q™ at a Level 3 Certification (or better), there have been **ZERO OBSERVATIONS** of non-compliance of the methodology used. A short, non-exhaustive, list of inspectors / auditors includes:

Agencies That Have Inspected SPRIITS™ / C3Q™ Sites – NO OBSERVATIONS

- US Drug Enforcement Agency - DEA
- EU European Medicines Agency - EMEA
- US Environmental Protection Agency – EPA
- UK Medicines and Healthcare products Regulatory Agency – MHRA
- US Food and Drug Administration – FDA
- US Occupational Safety and Health Agency - OSHA

Companies That Have Inspected SPRIITS™ / C3Q™ Sites – NO OBSERVATIONS

- | | | |
|------------------------|-----------------------|--------------------------|
| 3M Pharmaceuticals | Elan Pharmaceuticals | Procter & Gamble |
| aaiPharma | Eli Lilly and Company | Pharmaceuticals |
| Adolor Corporation | Endo Pharmaceuticals | Purdue Pharma L.P. |
| Ajinomoto Co, Inc. | Forest Laboratories | Regis Technologies, Inc. |
| Amgen, Inc. | InterMune, Inc. | Rhodia, Inc. |
| Amylin Pharmaceuticals | Johnson & Johnson | Ricerca Biosciences |
| Astra-Zeneca | Pharmaceutical | Sanofi-Synthelabo |
| International | Research and | Schering Plough Animal |
| Aventis | Development, LLC | Health Corporation |
| Barr Laboratories | Novartis | Scios, Inc. |
| Boeringer Ingelheim | Otsuka America | Sepracor Inc. |
| Pharmaceuticals Inc. | Pharmaceutical, Inc. | Shire Pharmaceuticals |
| Bristol-Myers Squibb | Pfizer, Inc. | Teva Pharmaceuticals |
| CIMA Labs, Inc. | Pharmaceutics | Xenoport, Inc. |
| Clay-Park Labs, Inc. | International, Inc. | Yanamouchi Pharma |
| CV Therapeutics, Inc. | | |

So, if your question is, “Why should we risk an unproven / unaccepted methodology?”, the likely answer is, “Don’t ask us! Your company has *already accepted* SPRIITS™ / C3Q™, a proven, effective, LOWER COST and LOWER RISK methodology.”