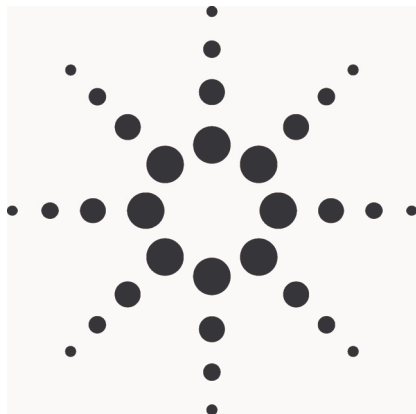




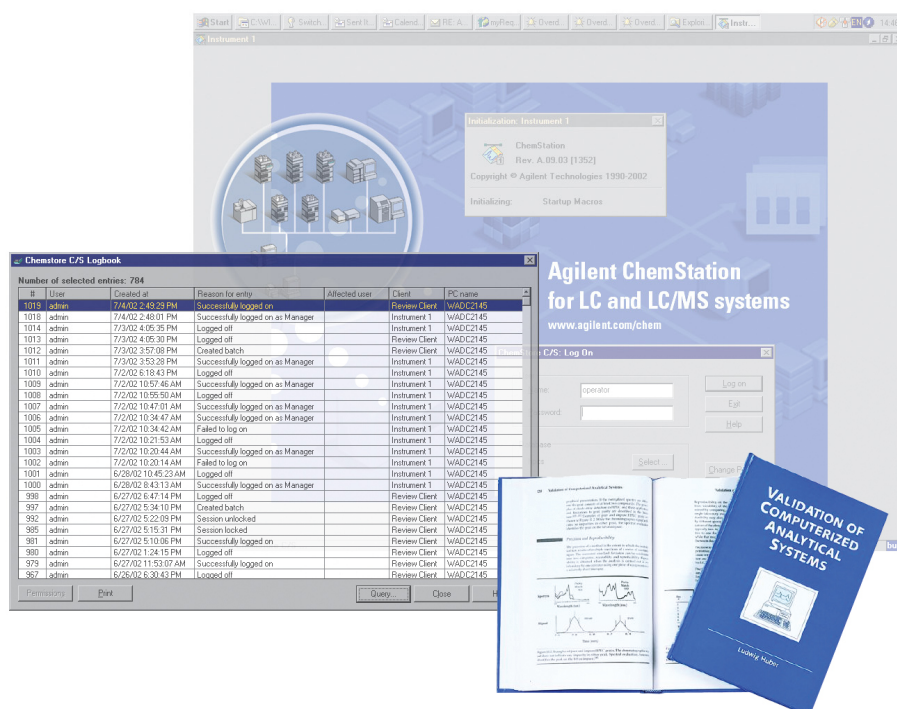
# RunTime Pharma C/S Bundle

## 21CFR Part11 Compliance for the Small Lab

### Technical Overview

Chromatographic Data Systems (CDS)

Author: Hans-Peter Bluhm



### Introduction

The U.S. food and drug administration (FDA) most recently shifted the focus of their inspection activities from manufacturing process to analytical laboratories. Computers and especially critical data generated by the computer are a major concern.

On August 20, 1997, the FDA published 21 CFR Part 11, covering Electronic Records and Electronic Signatures in final form. Rule 11 especially influences many operations in pharmaceutical QC laboratories.

This rule of course has a severe impact on the Agilent ChemStation. Neither the chromatography ChemStation for LC, CE, GC and MS nor the current UV-Vis ChemStation are compliant to this rule. The Agilent ChemStore server solution, designed for an extensive Client/Server environmental, complies perfectly with this requirement, for example identification of the operator, storage of methods, raw data etc.

For smaller labs that need to comply with today's FDA's 21CFR Part11 rule but do not have the resources to manage a Client/Server system, the new Agilent RunTime Pharma C/S is the optimized solution.

## **Description and Functionality**

Agilent RunTime Pharma is a Run-Time version of the popular ChemStation Plus Client/Server system.

Agilent ChemStore C/S is a scalable chromatographic database for Agilent ChemStations. It provides a means to easily organize, review and approve analytical data based on study and sample information. Agilent ChemStore C/S supports the users' data review process offering statistically result summaries, flexible control charts, cross-sample reports and documented data archiving and restoring. These services also aid users in doing on-going system suitability testing. The Agilent ChemStore C/S server database can be used as a central place for data storage of all analytical data including methods, sequences and the raw data. This data storage also satisfies the requirements for data handling in a regulated environment including the detailed requirements of the U.S. Food and Drug Administration for electronic records and electronic signatures, known as 21CFR Part 11.

The RunTime package also includes the Agilent ChemStation PlusSecurity Pack—designed to support the requirements of 21 CFR Part 11. It uses a relational database based on the ChemStore C/S database for secure result data storage, data review and electronically signing off runs. Login and Password Protection

- Password Policies
- Application Based Timeout and Lock
- AuditTrails on all Raw and Meta Data
- Complete Instrument Logbooks
- Data, Method, Sequence Versioning
- Built in Calculations (in DB)
- User Based Administration and Policies
- Data Integrity

- E-Signature functions for Data Review
- Upgradeable to full Version ChemStationPlus
- Built in Control Charting and Reporting
- Built in Archive Functions

### **The Agilent RunTimePharma C/S Bundle contains the following:**

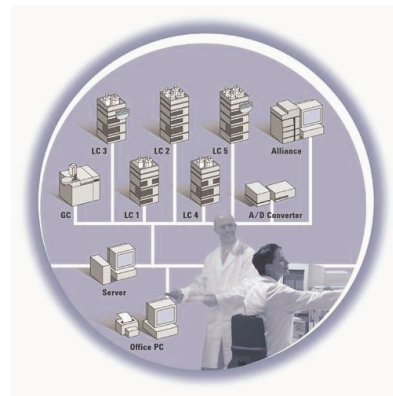
Dual, 3.3 GHz Intel Xeon processor, tower, 1 GB RAM, 5 x 36 GB Hot Pluggable Disks, 6 PCI-X slots, 17inch Monitor, DLT Tape Drive, integrated 10/100/1000 Ethernet, 3 year limited warranty, including prefailure war-ranty, Windows 2000 Server w/5 client license.

Agilent reserves the right to replace the server with equivalent or higher configuration.

- ChemStation Upgrade Software A.09.01 or higher
- ChemStore ORACLE Server Software License
- Security Pack Software License
- 4 ChemStore Client Software Licenses
- Installation, IQ and OQ of Server and up to 4 ChemStations (and or 4 Instruments)
- Onsite Admin Training (2 Users)
- Onsite User Training (4 Users)
- Network HUB and 5 LAN Cables, 10m each
- ChemStation Data Analysis Software is not included, purchase seperately

### **Optional:**

- 4 additional clients on the same order
- Integration into corporate network
- Additional instrument per ChemStation



- Return credit for existing ChemStation Plus Security Pack workstations
- Backup & Recovery Service includes Veritas Backup Exec Server Edition for NT/2000s

### **Assumptions and Exceptions**

- System is installed as standalone LAN (no corporate connections, Novell, etc.) Option for corporate connection available
- All instruments need to be located close enough to install with the delivered cables.
- ChemStations using revision B.01.01 or later (Upgrade Software is included).
- Backup familiarization for Cold Backup Strategy
- ChemStation instrument Specifications apply (i.e. number of instruments per PC) – Option for second instrument available
- Installation and training will take place during the same visit
- Warranty for non-Agilent equipment is handled by the original vendor.

### **Client Chemstation Specifications must meet the following Requirements**

- ChemStationPlus Client Ram: 256+ Megabyte for 1 instrument; 256+ Megabyte for 2 instruments ; 512+ Megabyte for 3 instruments
- Minimum 450MHz Pentium III CPU
- Minimum 1024 x 768 display resolution



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- Minimum 4 Gigabyte hard disk space
- Network Interface Card 10/100 Mbit, RJ 45
- MS Windows 200 Workstation or Windows XP
- Service Pack 4 (Windows 2000) Service Pack 1a (XP)
- MS Internet Explorer 5.5
- All disk volumes use NTFS
- Time zone, time and date are set correctly
- Disk defragmentation software installed on PC.

### **Ordering Process**

In order to customize this solution the following order process has been suggested:

1. Fill in the Sales Rep (FE) name and Customer name and address in the FAX sheet on the last page of this document.
2. Indicate which Options are required. This is necessary to make sure that the "Proposal" generated is accurate and reflects the customers requirements.
3. Fax the completed form to E-PSO Waldbronn.

E-PSO will then send you a final proposal" which you should share with the customer. The proposal describes what the solution is and the responsibilities of the customer and Agilent.

### **Acknowledgements:**

Hans-Peter Bluhm  
(PSO Manager Europe)  
Klaus-Rüdiger Bärwald  
(NDS Specialist)

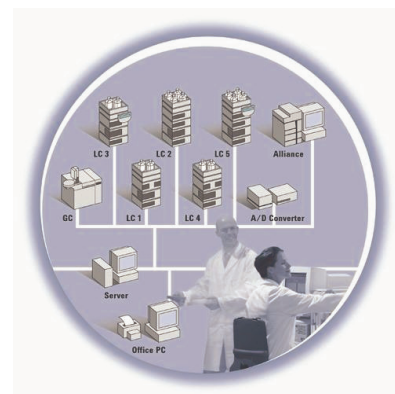
### **Further information**

As one of the leaders in Network Data System Solutions for the analytical laboratory, please check out our web site at

<http://www.agilent.com/chem>

*For details about this service contact:*

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**RunTime Pharma C/S Bundle**  
**21CFR Part11 Compliance For The Small Lab**

**Request for Proposal – Form sheet on last page**

FAX to:        Contact:        Birgit Kreid / Elsa Schäfer

Address:        Agilent Technologies Deutschland GmbH  
European Project Services Organisation (E-PSO)  
Hewlett-Packard-Str. 8  
76337 Waldbronn, Germany

E-Mail:        pso\_europe@agilent.com ☎ +49 (0) 7243 / 602-275

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# RunTime Pharma C/S Bundle

21CFR Part11 Compliance For The Small Lab

FAX or Email

To: Birgit Kreid / Elsa Schäfer  
E-Mail: pso\_europe@agilent.com  
Fax Number: +49 (0)7243 / 602-155

## Please prepare a Proposal for the following Customer

Customer Contact: ..... Phone: .....

Customer Address: .....

E-Mail Address: .....

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Agilent Representative Name / E-Mail: .....

| Description                                                                                                                                                                                                                                                                               | Include in Proposal | Quantity |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------|
| <b>RunTime Pharma Bundle</b> : Runtime version of ChemStationPlus C/S: Product includes; Server with DLT tape, 4 Clients lic, Security Pack for 21CFRPart11, Installation, IQ/OQ, OnSite Admin and User Training, 4 Lan Cables, 1 hub.<br>(Existing ChemStations must meet client specs.) | ✓                   |          |
| <b>Option 201:</b> 4 additional clients                                                                                                                                                                                                                                                   |                     |          |
| <b>Option 202:</b> Installation into existing Corporation LAN                                                                                                                                                                                                                             |                     |          |
| <b>Option 203:</b> Backup & Recovery. Includes Veritas SW                                                                                                                                                                                                                                 |                     |          |
| <b>Option 206:</b> Additional instrument per ChemStation                                                                                                                                                                                                                                  |                     |          |
| <b>Option 207:</b> Return credit for One Client with ChemStation Plus Security Pack workstations                                                                                                                                                                                          |                     |          |
| <b>Option 208:</b> Return credit additional client                                                                                                                                                                                                                                        |                     |          |

**REQUESTOR / Technical O.K.:** \_\_\_\_\_  
Name, Phone, Date



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