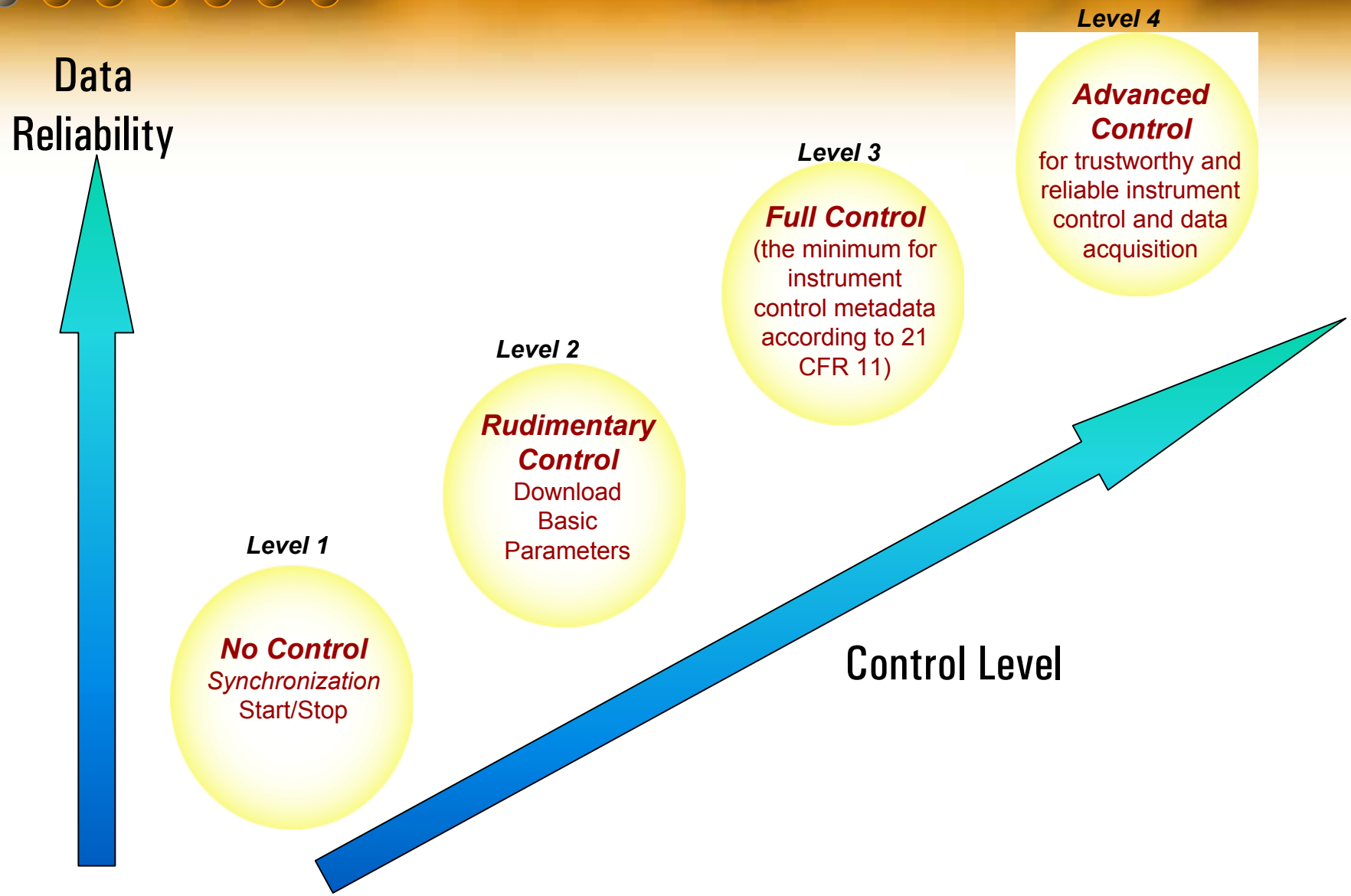
Welcome to our E-Seminar:

Compliant Multi-Vendor Instrument Control using Agilent GIC

Levels of Instrument Control



Compliant control: Level 3 and Level 4

Level 3

Full Control
(the minimum for instrument control metadata according to 21 CFR 11)

Level 3 allows for

- Bidirectional communication between instrument and controller
- Full execution of native „system method “
- Ongoing system monitoring from control software during acquisition
- Basic error information (connection lost...)
- Electronic documentation of all acquisition „meta data“

Level 4

Advanced Control
for trustworthy and reliable instrument control and data acquisition

Level 4 offers all level 3 features PLUS

- Error resistant communication protocol (for time interval ≤ 1 min)
- Documentation of local method modifications in control software
- Instrument driven preventive maintenance configuration and management (e.g. EMF)
- Advanced error documentation (leaks, network communication losses…)
- Advanced documentation of all system information in logbooks during acquisition
- Full system qualification (hardware, software and network connections)

Level 4 Instrument Control (Definition)

- Active handshake between software and instrument
- Supports advanced tagging of components, e.G. Column-id tags, automatic tracking of serial and product numbers, electronic instrument log-book
- Advanced error detection and diagnostics functions (e.G. Self diagnostics or early maintenance feedback (EMF)

Level 4

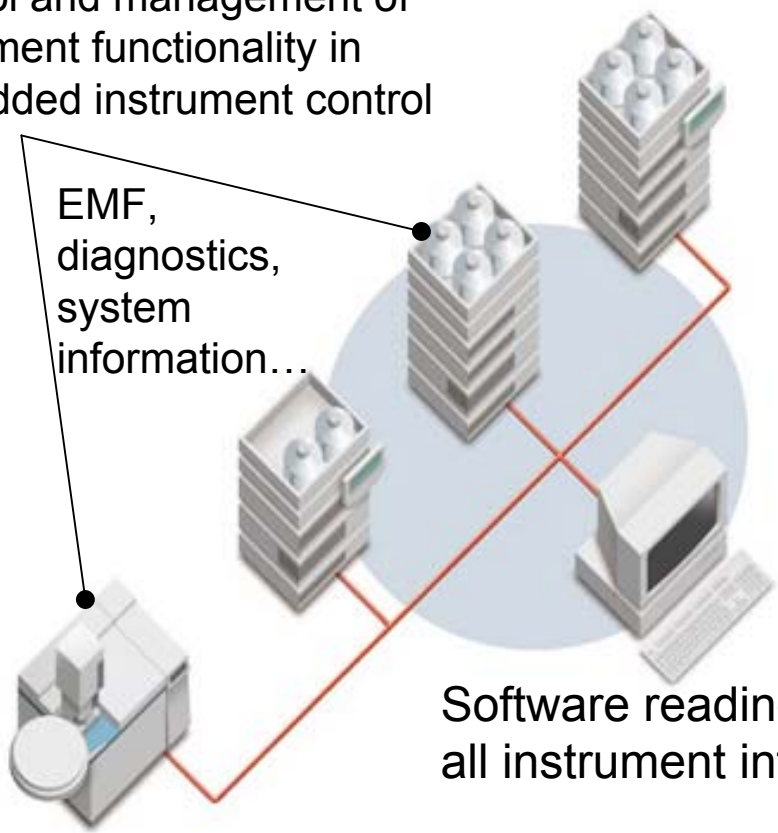
Advanced Control
(+ diagnostics, handshake, EMF etc.)

Impact on part 11
➢ Trustworthy, reliable and reproducible execution of data acquisition independent of current data system load in the spirit of Part 11 ➢ Validation: facilitates the execution of instrument qualification and preventive maintenance ➢ Qualifies for device checks required by the rule ➢ Guaranteed and reproducible execution of data acquisition independent of current data system load (facilitates the qualification of data integrity and traceability)

Level 4 building blocks

Control and management of instrument functionality in embedded instrument control

EMF, diagnostics, system information…



Software reading and managing all instrument information

Level 4 puts requirements on instrument AND software –

it is possible offering level 4 control to other parties hardware but it is impossible applying a software package to a 3rd party and achieve level 4

3rd party instrument control situation

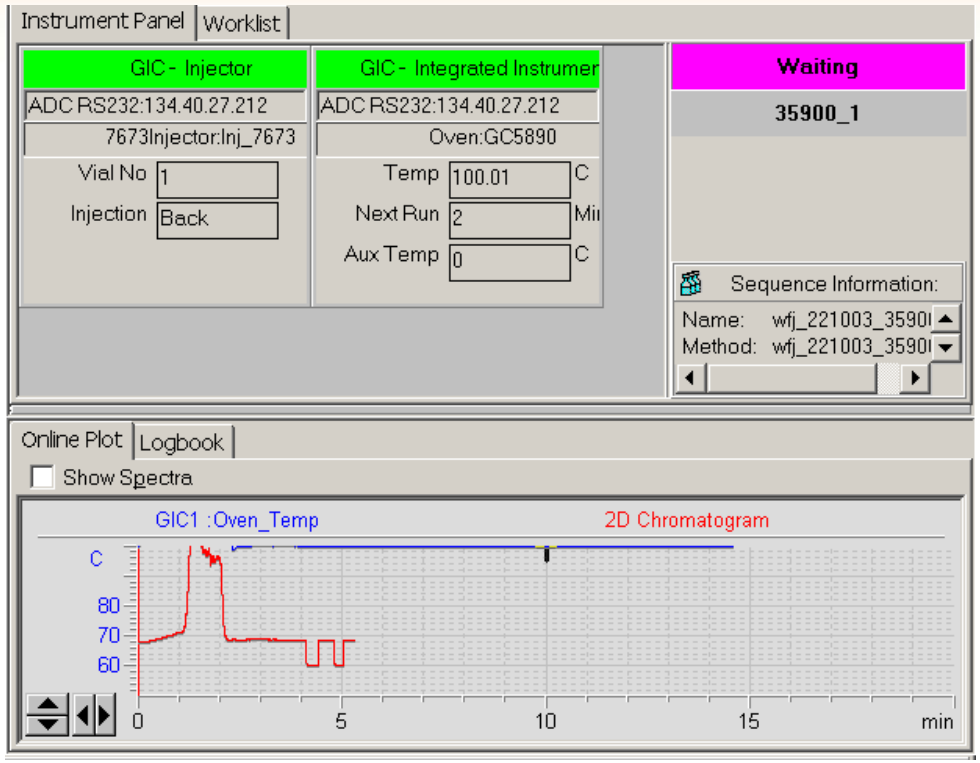
The situation:

- many laboratories have equipment from multiple vendors but want to connect all instrumentation to one data system
- Laboratories frequently use “mixed” systems of standards plus an additional external device
- All laboratories also must validate their software and hardware
- Instrument user require validated control of all instruments – no reverse engineering or hacking of control codes

Customer requirement: Offer Instruments control for the complete laboratory instrumentation

3rd party control through A/D versus GIC

- Most data system use standard A/D converters to control non-proprietary instruments. This approach has multiple limitations:
  - It requires the user to set all acquisition parameter through the local instrument control outside of the software
  - Data retrieval from the instrument is limited to one signal channel and start/stop information – no meta data or system information available
  - No bidirectional communication between instrument and software
- ***=> IT IS NOT COMPLIANT***



Cerity GIC allows for compliant level 3 instrument control of any 3rd party instrumentation

Top Requirements

- "Plug and Play" driver (VSIA) installation (NO installation of any components on review clients)
- Standard communication interface based on RS 232 (35900E as communication interface) Future plans: multi-port RS232 card, GP-IB etc.)
- Flexible instrument configuration through standard Cerity U/I's
- Standardized U/I components configurable via VSIA XML file
- VSIA developer kit for Agilent and partners
- Support for software IQ and OQ/PV

VSIA = Vendor Specific Instrument Adapter

3rd party instrument control - solution

The solution: Cerity GIC

- Provide “level 3” instrument control of 3rd party chromatographic instruments for Cerity.
- Use printer driver approach: Split instrument control into a generic Cerity portion and an instrument specific “VSIA driver” portion
- Allow ‘plug and play” device driver installation and configuration without the need of installing a new Cerity revision
- Offer full IQ and OQ for software and instrument control
- Minimize the development time and costs of 3rd party device drivers.

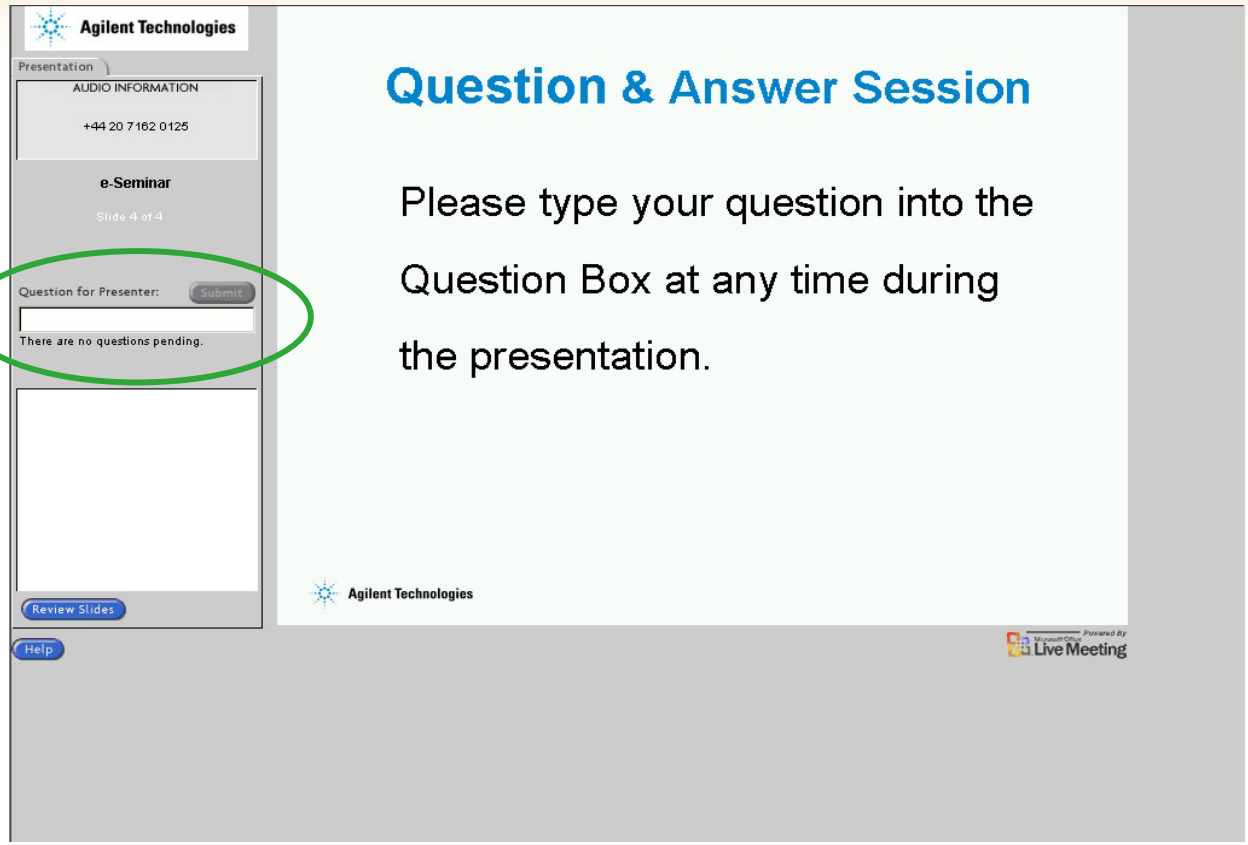
Customer requirement: Offer Instruments control for the complete laboratory instrumentation

Controlling Multi-Vendor Instrumentation

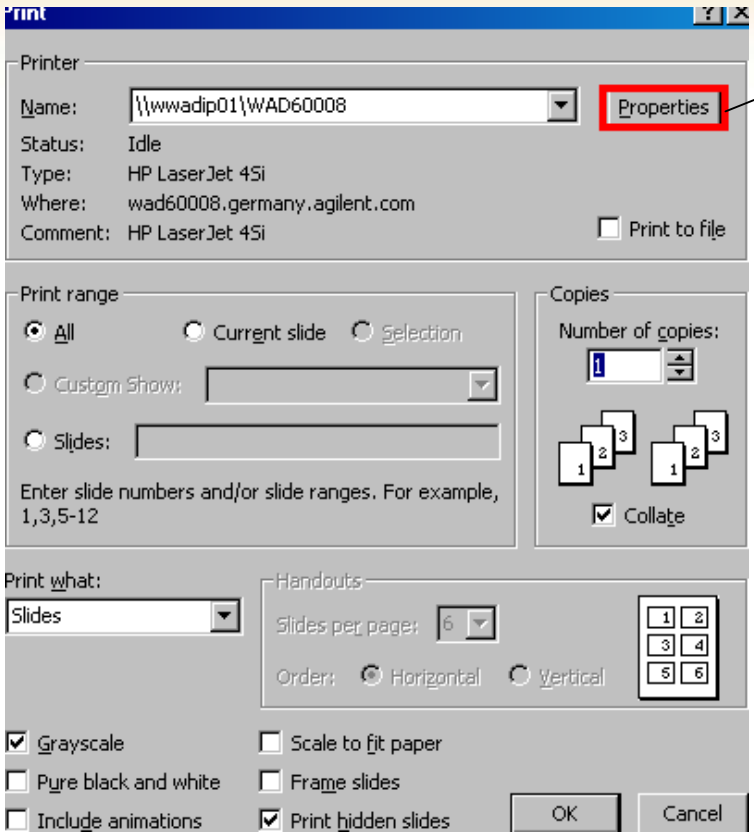
Cerity Generic Instrument Control Module (GIC)

- A generic framework for bi-directional control of third party instrumentation
- Only signal acquisition through A/D converter – full system control through generic RS 232 interface
- Bi-directional instrument control through serial interface
- Vendor Specific Instrument Adapter (VSIA) provided on request
- Requires communication protocols of the relevant devices

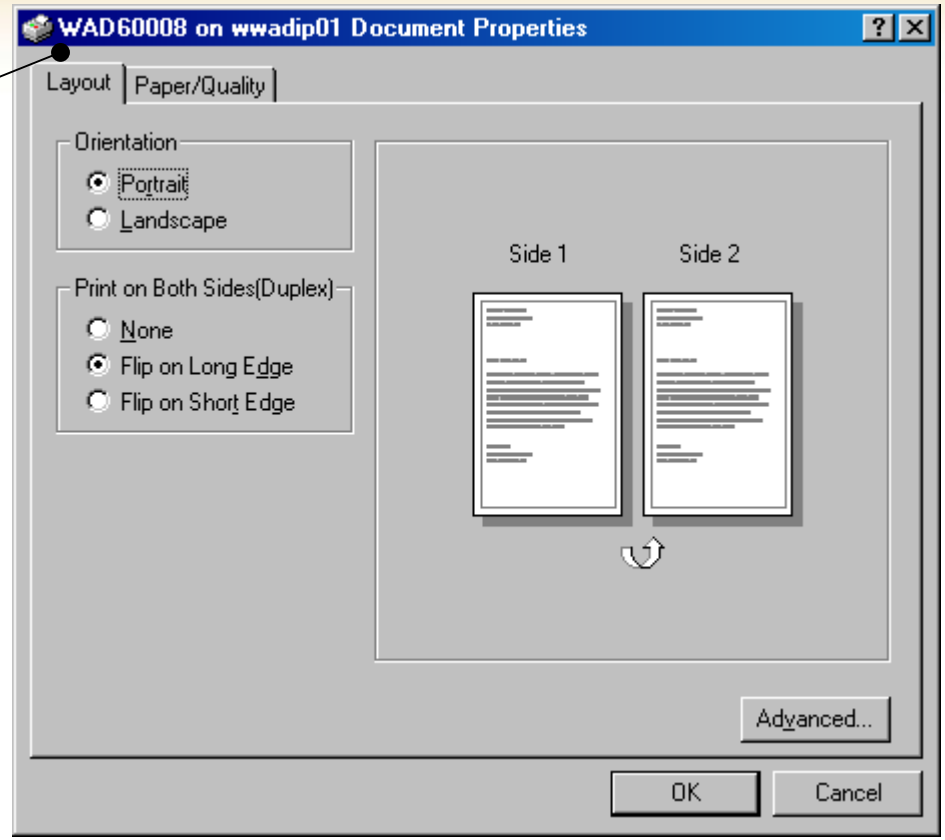
Break Number 1



Principle of GIC

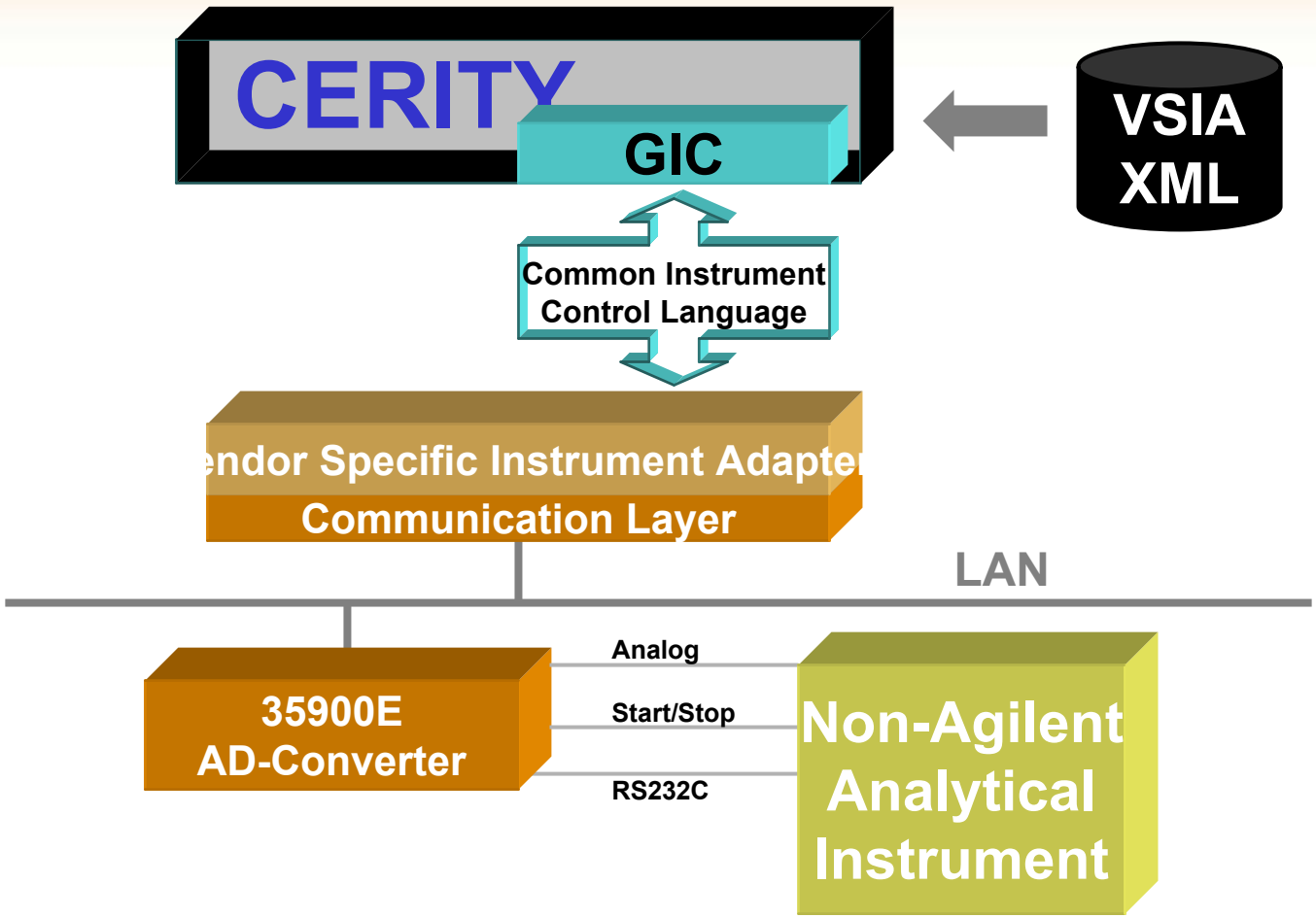


Common window for all printers



Specific window for each printer
(varies with printer type)

GIC Architecture Overview



GIC versus analog/digital

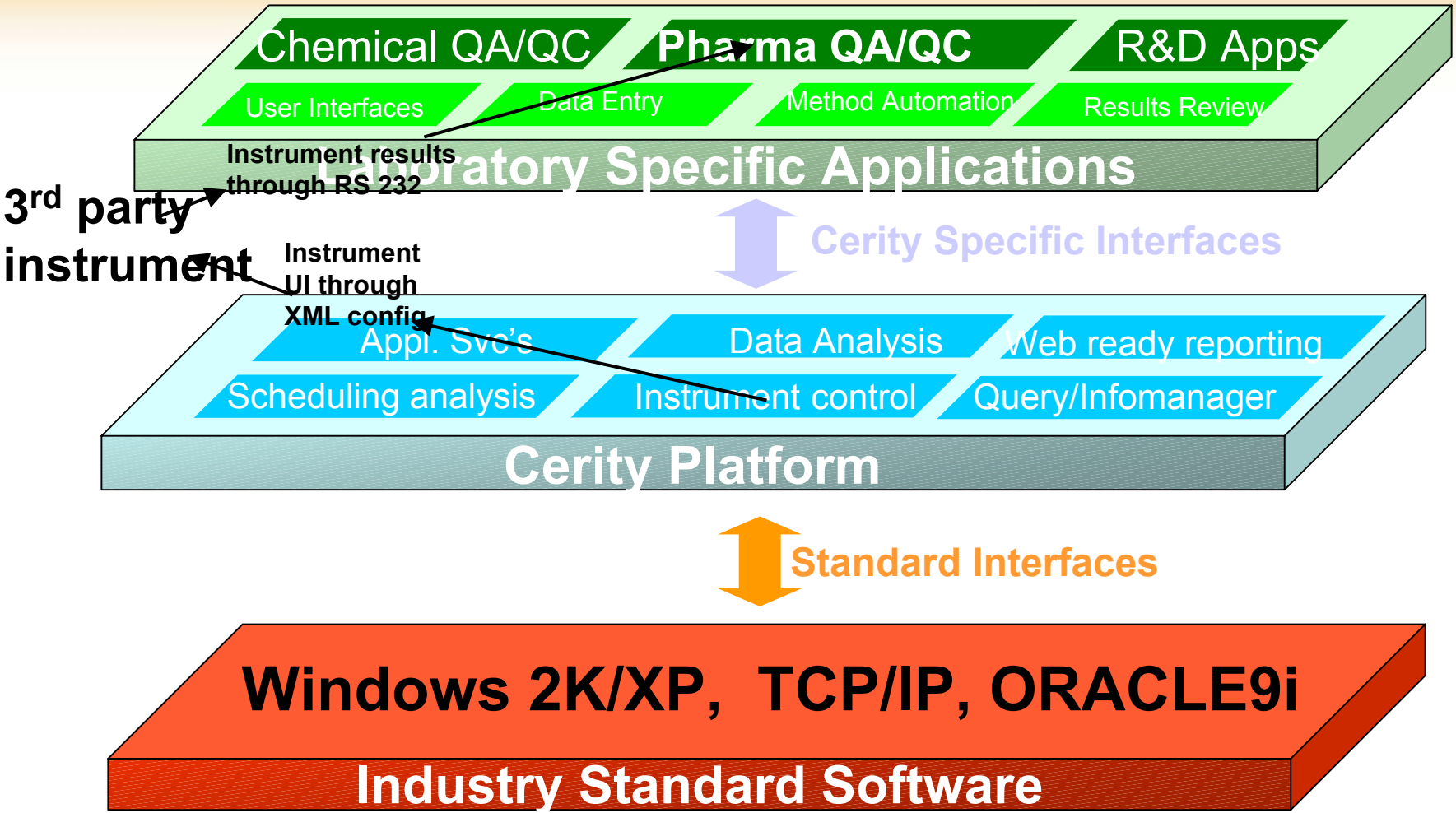
Analog/digital converters for control of non-proprietary instruments:

- No compliant instrument control
- No meta data or system information available
- No bi-directional communication between instrument and software

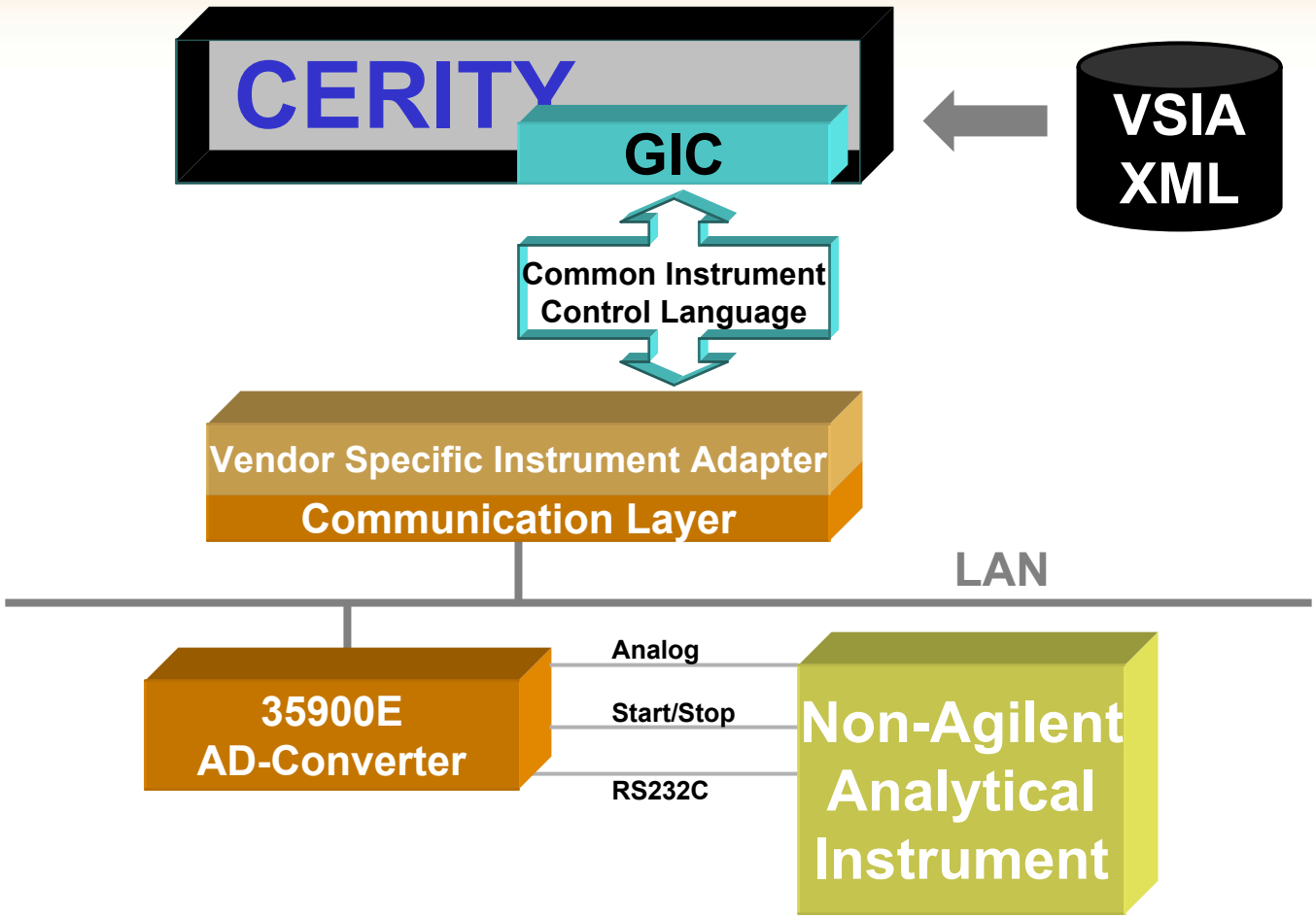
Cerity GIC - generic interface for full method download and execution:

- Fully compliant level 3 instrument control
- All instrument actions are tracked in the Cerity instrument logbook
- Bi-directional communication between instrument and software and result signal(s)

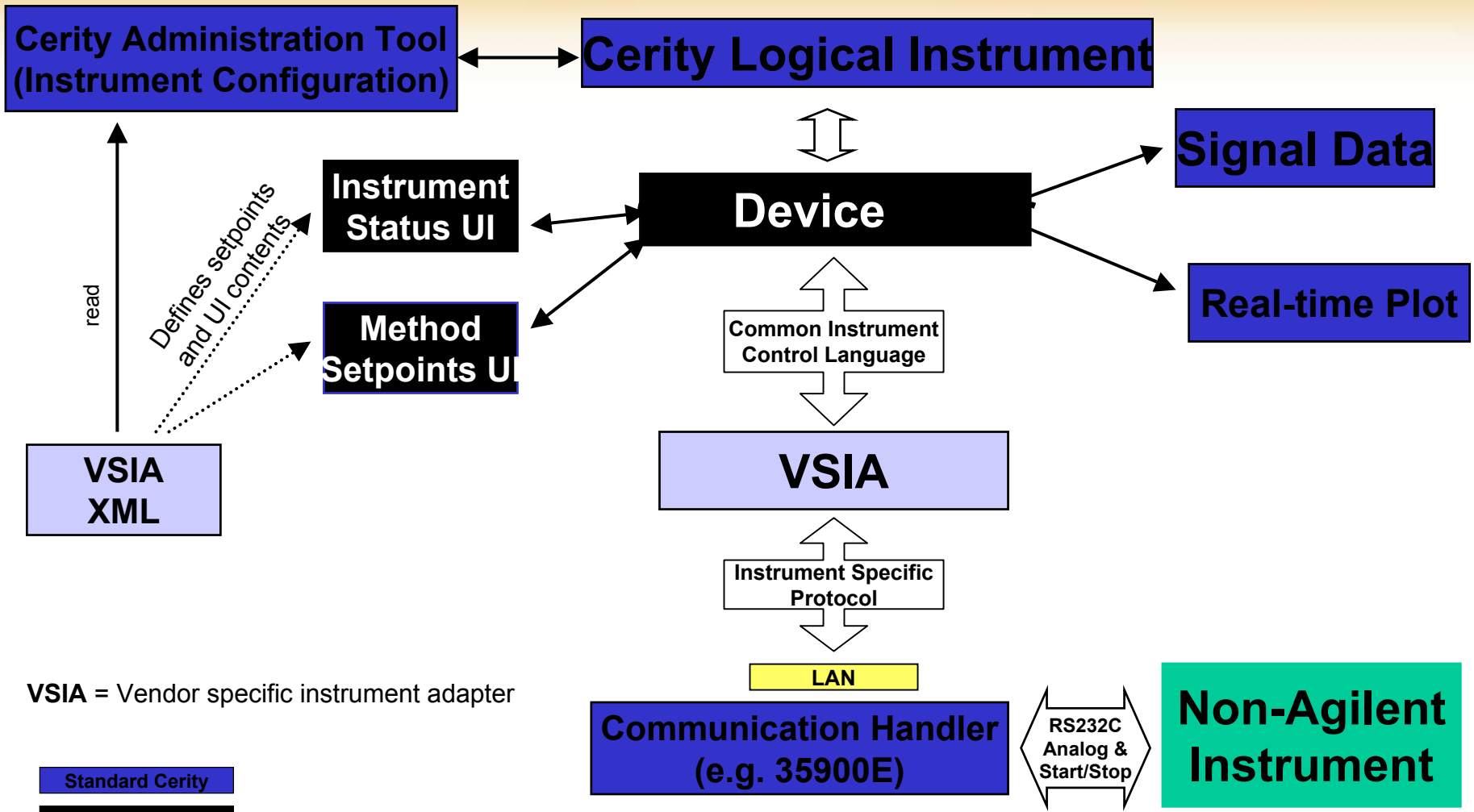
Modular Software architecture



GIC Architecture Overview



Cerity GIC Architecture



VSIA = Vendor specific instrument adapter

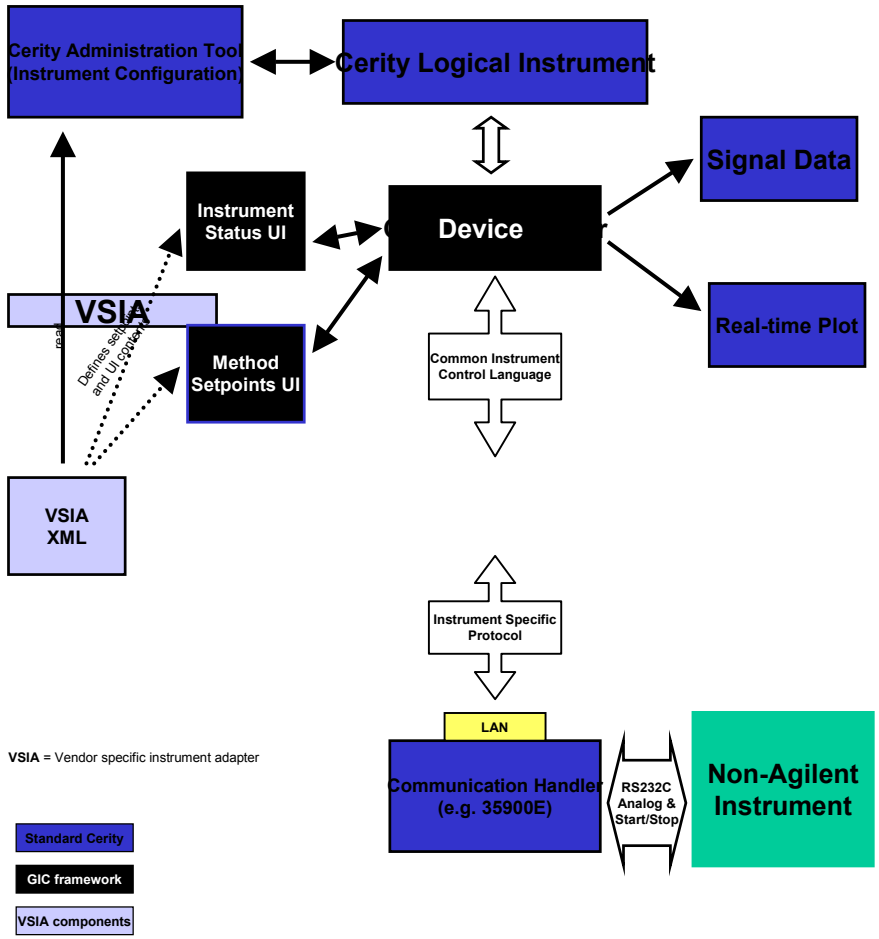
Standard Cerity

GIC framework

VSIA components

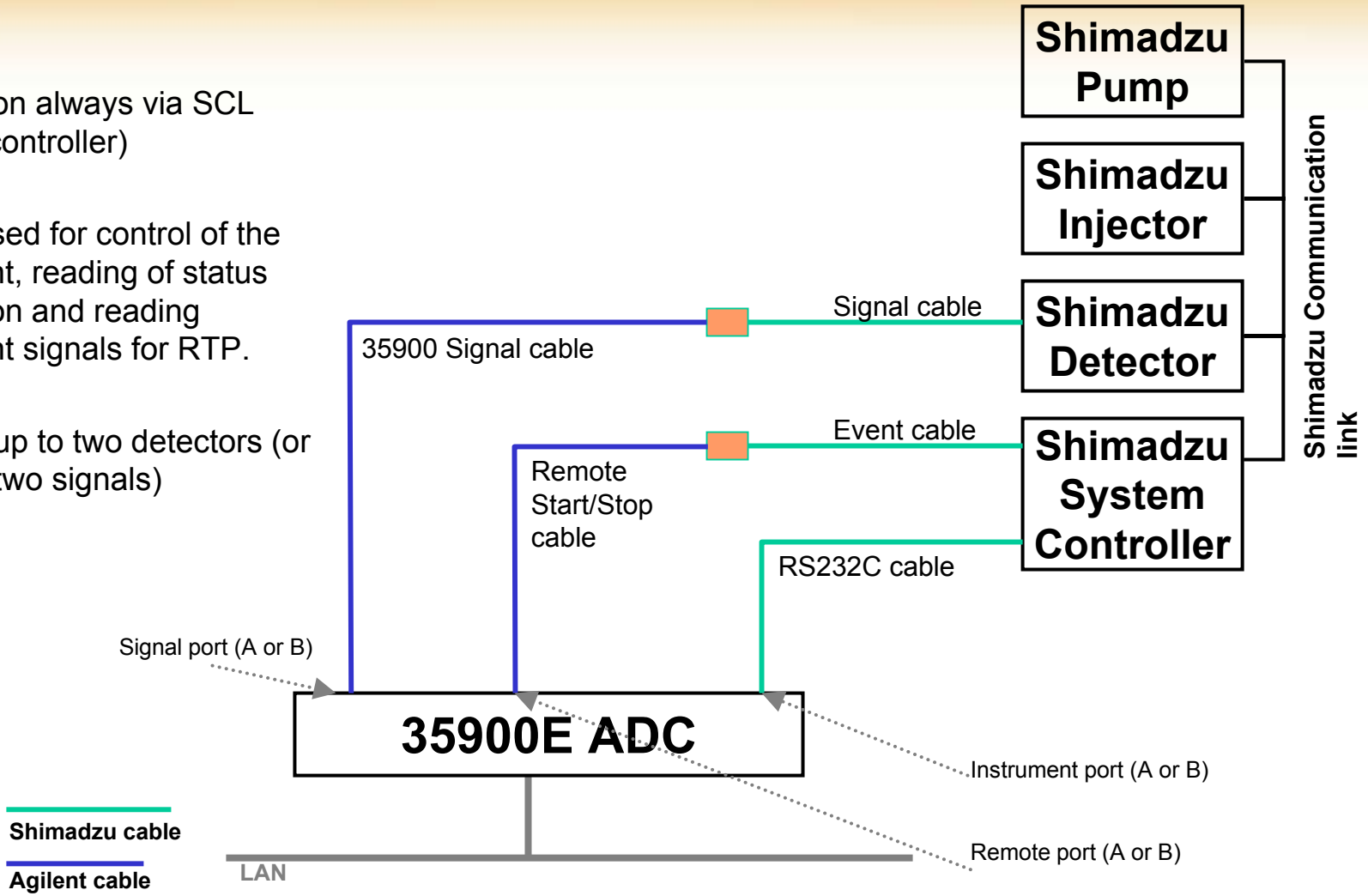
Advantages of Cerity GIC Architecture

- Independent system modules allow combining multiple instrument modules into one “logical instrument” (e.g. Agilent 1100 plus 3rd party detector)
- Modular approach makes VSIA independent of actual Cerity core revision
- IQ and OQ of 3rd party system only requires VSIA validation once Cerity was validated



GIC Control of Shimadzu LC10Avp LC

- Connection always via SCL (system controller)
- RS232 used for control of the instrument, reading of status information and reading instrument signals for RTP.
- Connect up to two detectors (or one with two signals)



Controlling Multi-Vendor Instrumentation

- Cerity Generic Instrument Control Module (GIC) is a generic framework for bi-directional control of non-Agilent instrumentation
- Method download/actuals upload through RS 232 of A/D converter, Data acquisition through analog signal channel at initial release
- Bi-directional instrument control through serial interface
- Agilent or Agilent partner provides instrument-specific driver (Vendor Specific Instrument Adapter, VSIA) upon request
- Requires control codes (communication protocol) of the relevant devices

GIC Example

First Vendor Specific Instrument Adapters (VSIA)

- Agilent 5890 GC with 7673 Automated Liquid sampler
- Shimadzu 10A Class VP Series
- Future applications:
  - Non-Agilent sample introduction systems for GC and LC such as CTC, Gilson or Gerstel systems
  - Non-Agilent detection systems
  - Additional VSIAs for other vendor's instruments can be programmed through Agilent's consulting group or 3rd parties
  - …

Levels of Instrument control in Cerity

Instrument control with Agilent products (sold as Agilent parts):

- Level 4 for Agilent LC and GC (6890/6850) (extended to level 5 with NetQual)
- Level 3.5 for Waters Alliance systems
- Level 3 for Shimadzu LC 10A and 5890/7673

Instrument control through custom/non-Agilent VSIA products:

- Any other system through custom programming with VSIA developer kit
- or through Agilent consulting programming interfacing to Cerity through GIC

Benefits of Cerity compliant instrument control

- Compliant Level 3 Instrument control through GIC:
  - One shop solution for compliant instrument control of ~75% of worldwide HPLC market (Agilent 1100/1090, Waters 2690/2695 and Shimadzu LC 10A VP series (2D)
  - In addition GIC can bring a complete (analytical) instrumentation into compliance with one software application (If RS 232 communication ports are available) if instrument control codes are available to instrument owner)
  - Free combination of multi-vendor modules to one logical system
  - System designed for full IQ and OQ of all components

GIC next steps

- Step 1
  - Enhance communication protocol to generic RS 232 Com port (August 2004)
  - Change the program to speed up programming of the VSIA
  - Provide a “Device Driver Development Kit” to allow easy development and integration of instrument device drivers into Cerity by Agilent or 3rd party companies.
- Step 2:
  - Deliver further instrument drivers (ongoing)
  - Monitor instrument control language standardization efforts (LECIS)
- Step 3:
  - Expand the capabilities to 3D control