



# **A Novel Approach to Pharmaceutical Registration : Registration as a Service**

**September 27<sup>th</sup>, 2011**

# Registration as a Service

During the presentation, I will address the following questions:

- What is Software as a Service (SaaS)?
- What was our initial plan for implementing a registry system as SaaS?
- What issues did we run into?
- What were our responses and decisions to move forward?
- What does the final system architecture look like?
- What are our plans moving forward?

# Software as a Service – a definition

**Software as a Service** - *a software delivery model in which software and its associated data are hosted centrally (typically in the (Internet) cloud) and are typically accessed by users using a thin client, normally using a web browser over the Internet.*

- The application is hosted centrally, so new releases can be put in place without requiring customers to physically install new software.
- The application only has a single configuration, making development testing faster.
- The application vendor has access to all customer data, expediting design and regression testing.
- The solution provider has access to user behavior within the application (usually via web analytics), making it easier to identify areas worthy of improvement.
- Accelerated feature delivery is further enabled by agile software development methodologies. Such methodologies, which have evolved in the mid-1990s, provide a set of software development tools and practices to support frequent software releases.

# Why Software as a Service ?

- In 2009, GSK undertook a significant program to simplify it's IT landscape and reduce R&D IT spend.
- This effort resulted in a large program of work to replace or retire products that were expensive to maintain, or posed a risk to the company due to their age.
- The existing GSK registration system was identified as a potential system for replacement.
  - Registration Software was implemented long before current integration standards
  - Support for the product was expensive as it runs on legacy hardware
  - The Chemical cartridge upon which the application was based was being changed to the new Chemaxon standard adopted by GSK.
- As part of the Simplification effort, headcount was also reviewed, and the registrar staff was targeted for a 40% reduction.

# The selection Process

- When the registration systems was targeted for replacement, it was decided Registry would be a good tool on which to attempt a Software as a Service (SaaS) implementation.
- Then the specific IT project team determined the path forward:
  - Existing requirements were reviewed and revised
  - A RFP was prepared and distributed to multiple vendors
  - A paper review of the proposals and interviews were completed
  - An initial vendor was selected
- No other SaaS implementations had been undertaken within GSK R&D IT at that point.

## SaaS – Moving into uncharted waters

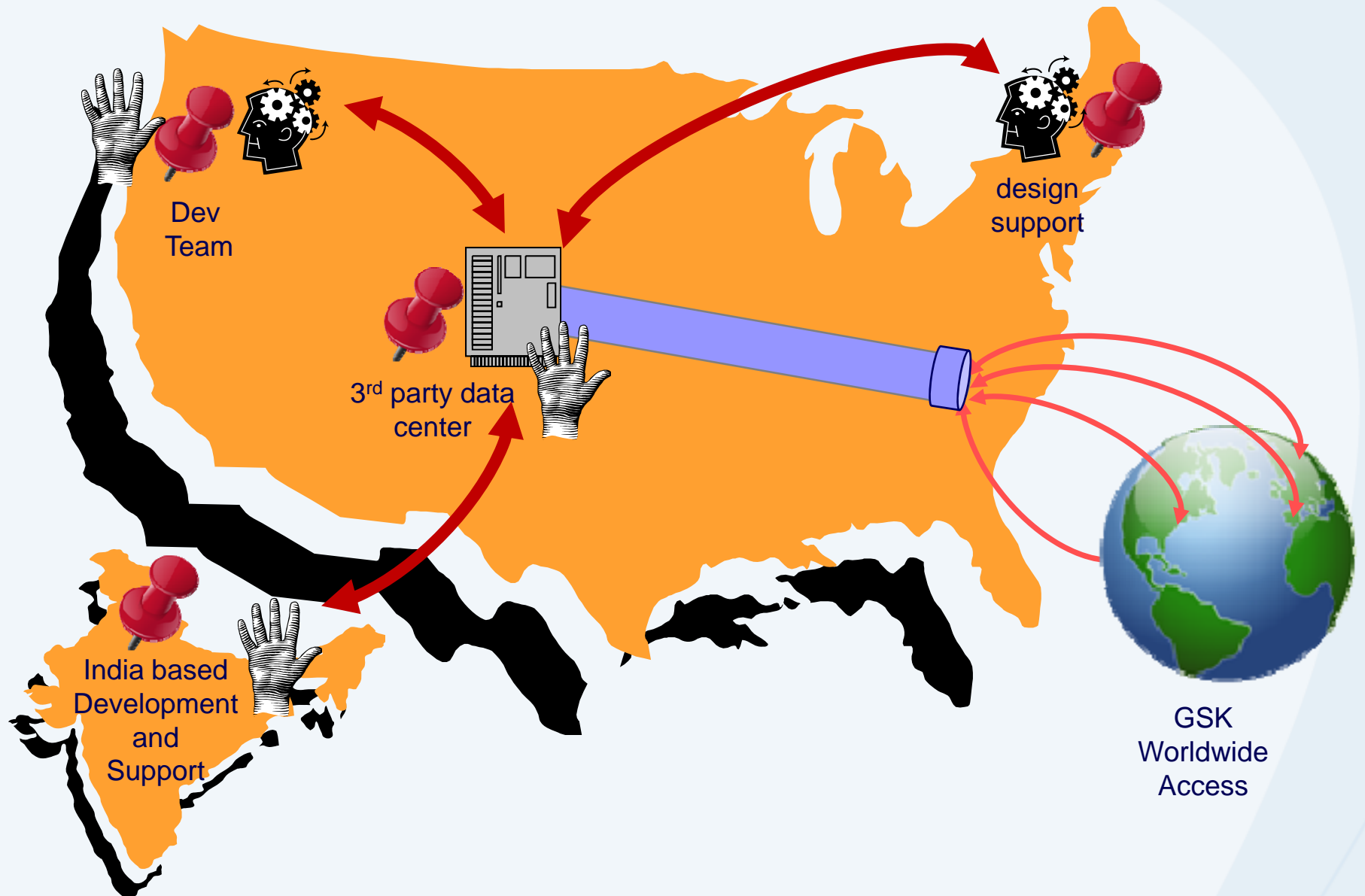
- In late mid 2009 GSK chose a supplier for the Registration as a Service (RaaS) project
- Chemaxon was not the initial choice
  - At that time Chemaxon did not have their own offering for a registration system
- GSK selected a vendor who was re-engineering their existing registration product and was open to a SaaS implementation
  - All support, development, maintenance, help would be managed by the vendor
  - GSK would access the application via the “cloud”
  - GSK would pay a yearly fee for a set number of compounds registered
  - Additional overages would be charged at a sliding fee rate

# Our initial idea for Registry as a Service (RaaS)

- The idea behind implementing registry as a service
  - Enable flexibility for moving Registrar resources external to GSK
  - Establish a “Fee for Service” arrangement for Registry (i.e. yearly costs would be based on number of registrations)
  - Reduce hardware support/maintenance
  - Reduce software maintenance



# The reality of the initial Implementation Proposal



# Working through the Contracts

- The GSK development team started discussing many technical/procedural issues:
  - SAS 70 compliance
  - Software Development Lifecycle Approach
  - Security
  - Support Plans
  - Liability

# The Liability Issue

- One topic that the GSK team had not fully considered prior to starting the project was the area of liability
  - How do you put a value on your entire compound collection?
  - When are you sure that the security model is adequate to protect it?
  - How do you get a vendor to insure the value you've assigned?
- Although the initial pricing proposal for a SaaS delivery of a registration service was quite reasonable, it did not cover liability insurance costs for any loss of IP.
- Once these costs were factored in, it became clear that the total cost would be much greater.

## An Alternate Approach

- Since the liability issue was challenging the success of the project, the GSK team began to look at alternatives to the existing proposal:
  - GSK had implemented JChem and switched over many of our internal web services
  - We had developed several new applications (Helium) with ChemAxon products and support and had developed a good working relationship with Chemaxon
  - The GSK technical team started investigating development of a registration system based on the Chemaxon tools
- In three months the developers had produced a working prototype and the GSK team saw real potential in the approach

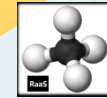
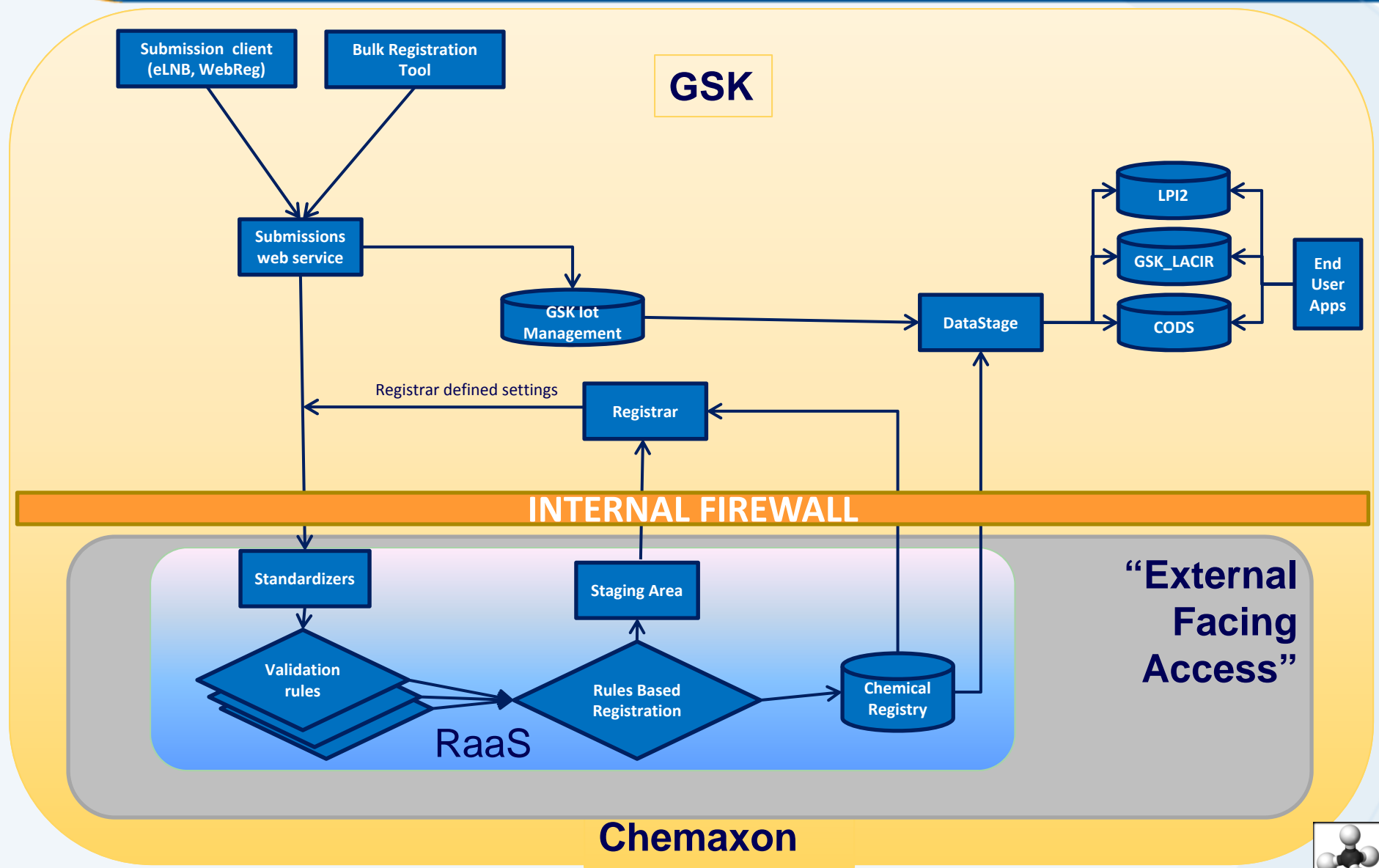
## Coming to compromise

- Once the working prototype was in place, the GSK team could see the benefits of working with Chemaxon as a SaaS supplier
  - Members of the team discussed the SaaS approach with ChemAxon
  - The group re-assessed what we were truly trying to get out of a SaaS delivery:
    - Lowered support and maintenance costs
    - Quicker turnaround of releases
    - Single payment structure based on # of compounds registered
  - We also recognized that the liability issues could be avoided if GSK data was protected at GSK Sites using GSK security.

# Progress

- As prototype development progressed, the GSK accepted that the Chemaxon approach would be the most sensible solution and most likely to succeed.
- Chemaxon became interested in taking the project on as a new addition to their product line.
- GSK realized that the issue of IP Security and Liability was not going to be easily solved, so the Team engineered a solution that would allow Chemaxon to have control over the hardware and software, yet maintain the application out of a GSK secured data center.
- The new configuration would allow Chemaxon the control they needed to manage the software as a SaaS product, but not expose GSK IP to unacceptable security concerns.

# Registration Domain – The Final Architecture



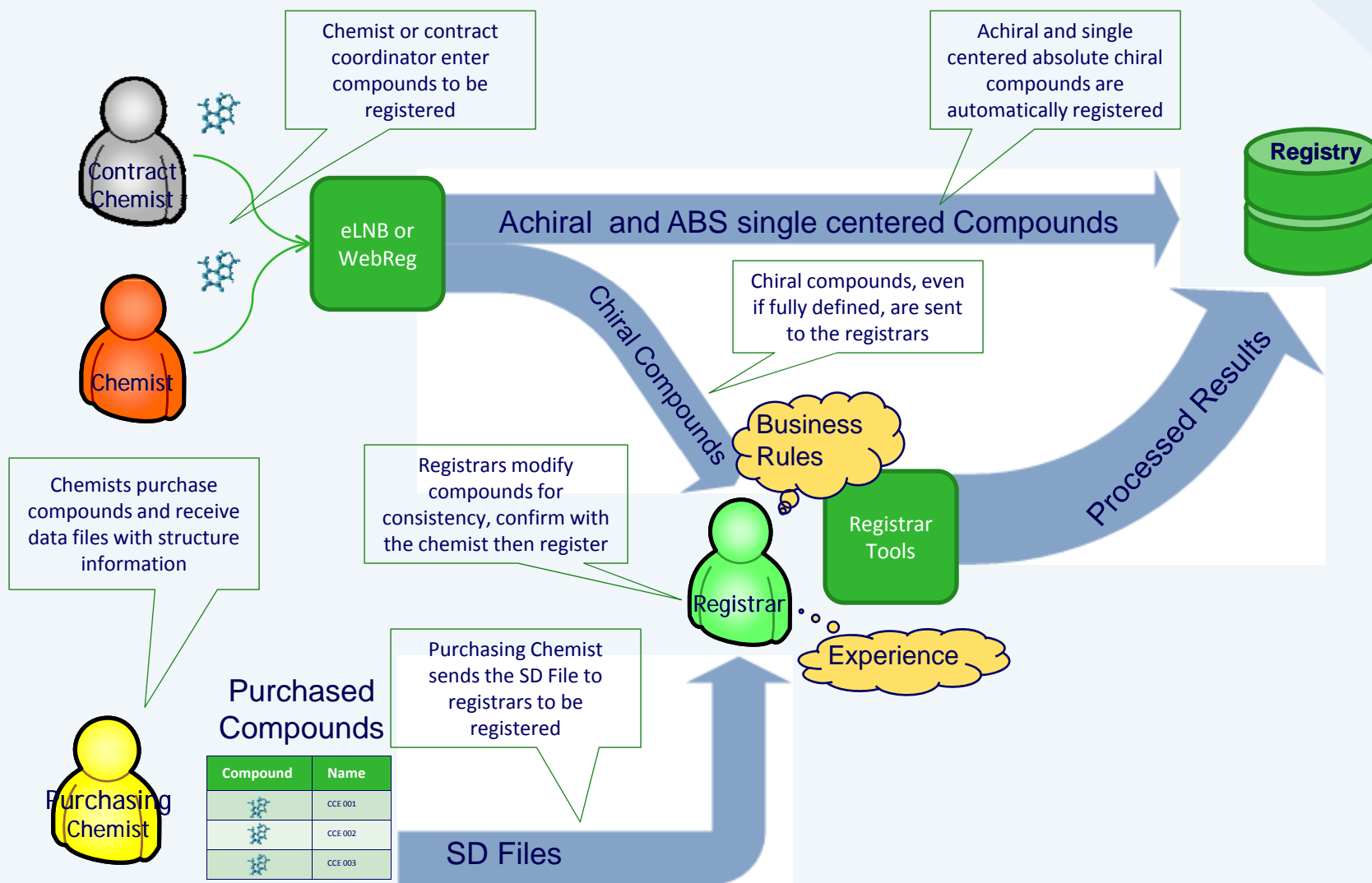
# The GSK Implementation

- Once the decision was made to go with Chemaxon, the GSK Team defined the following activities to be completed for a successful transition to the Registry as a Service (RaaS) model:
  - Migration of existing registry data
  - Re-integration of supported systems
  - Changes in Registrar Business Practice
  - Registrar acceptance
  - Changes in End user Business Practices
- In order to understand the magnitude of change required, you need to understand our previous registration system implementation.

# Issues with optimizing the current Registry process

- The current registration process has been developed over a 10 year period and is made up of a loosely integrated set of tools and utilities working in concert with the existing Registration system.
  - The system requires registrar to access SD-files on a File share to register
  - The various components are separate applications bolted together to provide the solution. (Cheshire, Registration Client, DB Triggers to create SD-Files, etc.)
- The tool has never been positioned as an 'End User' tool. It has always relied on the knowledge and business understanding of registrars to work efficiently.
- The current system does not allow for easy reconfiguration of automation rules to allow for further automatic registration of compounds
  - There are several different rules engines that need to be configured
- There are multiple points of failure in the overall process and it can be difficult to determine where the process 'Failed'.
- The current system is based on SMILES while all downstream systems expect MOL representation which has caused some difficulties in integration.

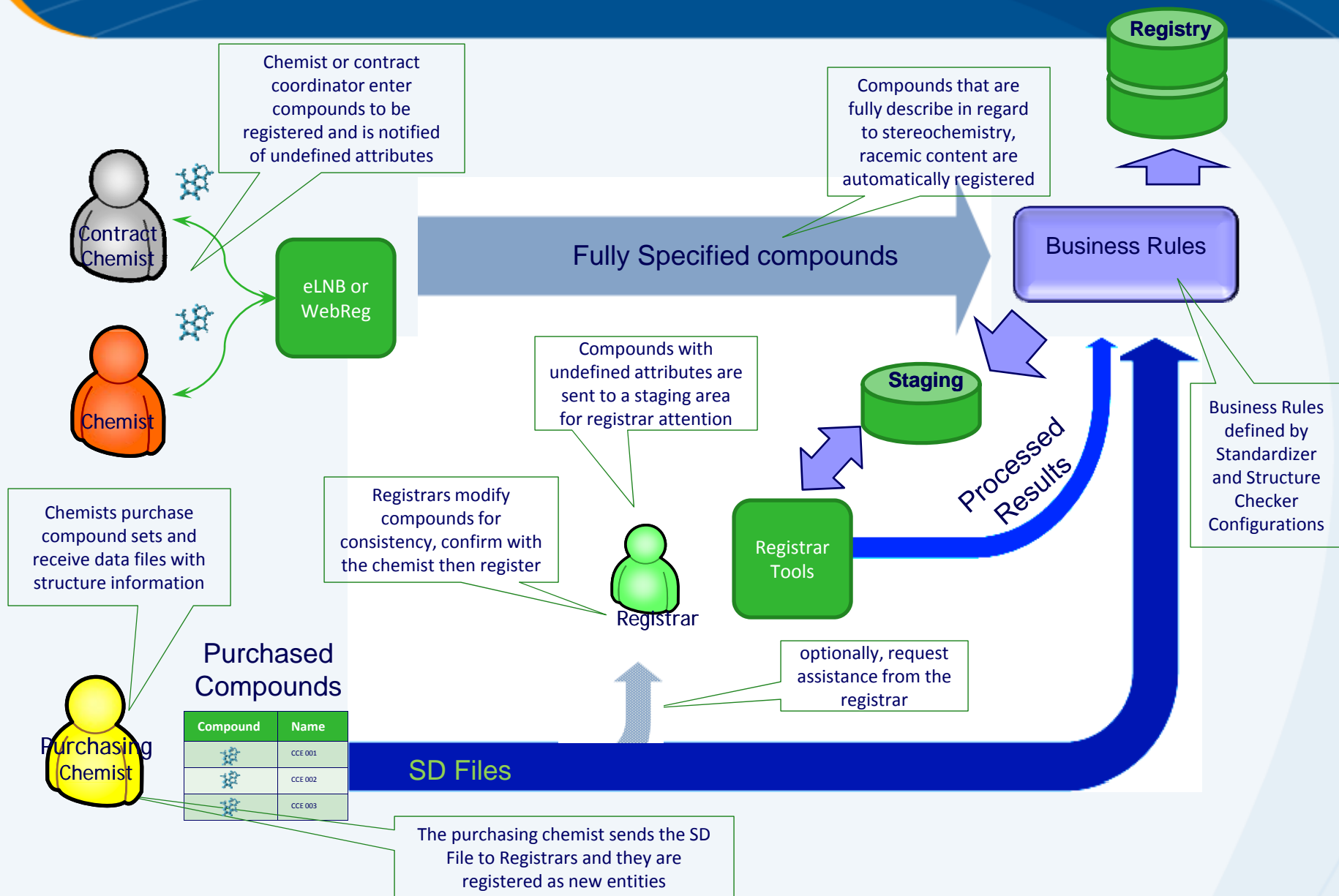
# Current Logical Flow of Submissions to Registry



# Activities and goals for Phase I

- Replace existing functionality with a more flexible alternative
- Get the application working with all the upstream and downstream components
- Developing confidence in the registrars who will “own” the system
- Tweak the Rules Engine to (at a minimum) produce the same level of automatic registrations
- Allow Purchasing Chemists to bulk load purchased compound sets

# Phase I - Laying the Groundwork

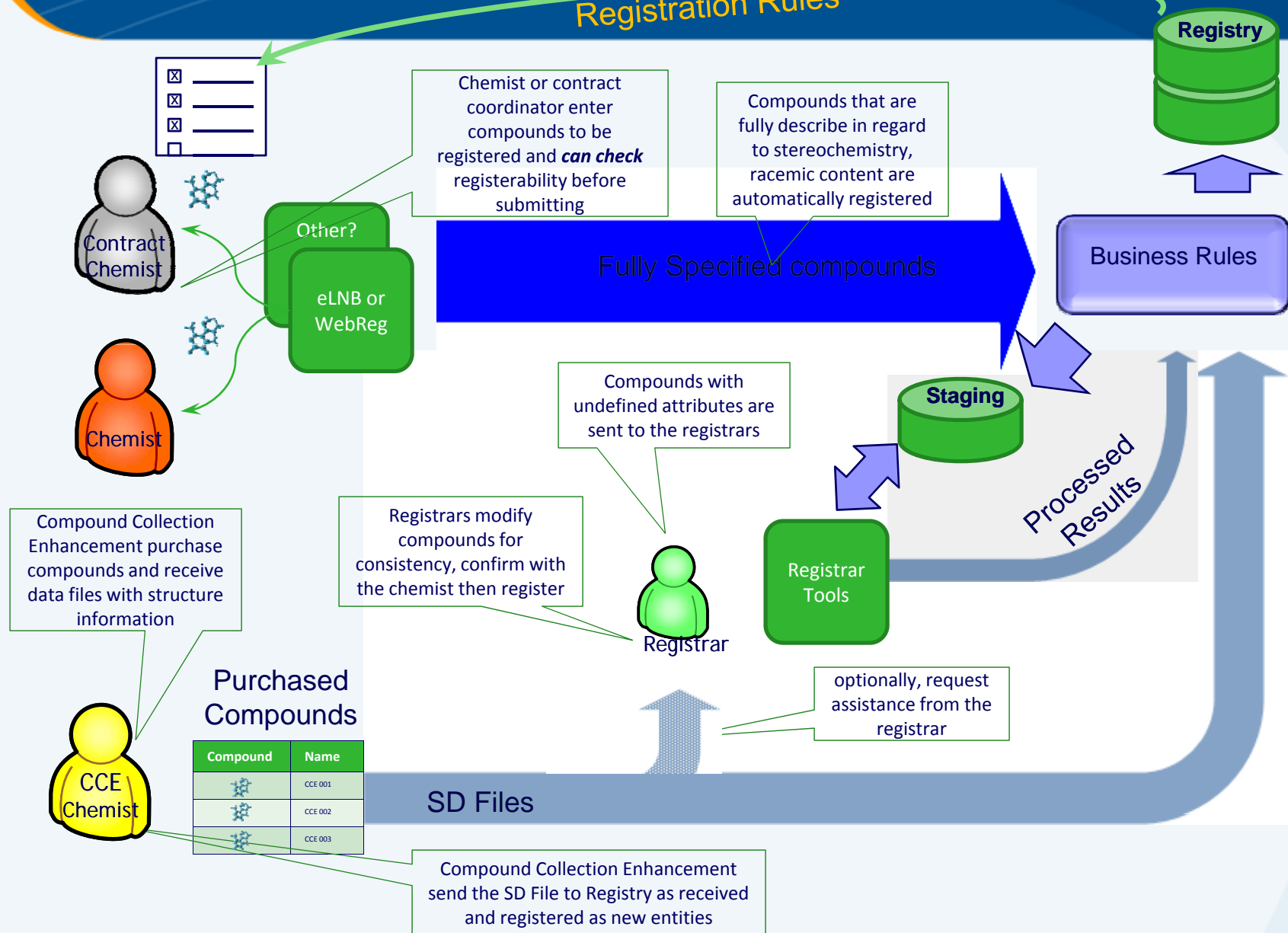


## Activities and Goals for Phase II

- Provide Feedback mechanism to chemists to assist in definition of structure to increase automated registration percentages
  - Automated registrations provide almost immediate feedback for further compound testing
  - Samples can be submitted to Compound Management faster
- Improve Registrar tools to aid productivity

# Phase II – Optimization

## Registration Rules



**Thank you for your attention!**

**Questions?**