Mammalian Cell Culture
Agenda

- What’s New
- Capabilities
- Custom Manufacturing
- Development Services
Our new mammalian investments are helping Lonza meet growing demand

Protein Design Services
- Potelligent™ CHOK1SV Cell Line
- Applied Protein Services
  - Immunogenicity, De-immunization
- GS System™ approaching results of 10g/L
- Lonza media/feeds for upstream development

Slough, UK
- Development and manufacturing expansion
- Targeted for completion 2012
- Light Path™ Services

Singapore
- Now available
Our mammalian cell culture production and services are industry-leading

**Products & Customers**
- Monoclonal antibodies and recombinant proteins
- Start-up biotech to large pharmaceutical companies

**Full-Service Offering**
- Cell line construction and PD to regulatory support
- Laboratory scale to commercial supply

**Industry-Leading Experience**
- Over 30 years in industrial mammalian cell culture

**Advanced Technologies**
- Stirred tanks, perfusion, airlift & single-use bioreactors
- GS System™, Epibase™, Potelligent® CHOK1SV
We offer a full range of development and cGMP manufacturing services

Discovery
- basic research
- disease discovery

Development
- drug discovery
- drug development
- clinical trials
- production

Manufacture
- lab supply
- clinical supply
- launch supply
- in-market supply
- media, buffers, reactors & process development

Distribution
- packaging
- marketing sales distribution
- support for regulatory submissions

- pre-development screening
- cell line construction
- cGMP cell banking
- process development
- scale up
- cGMP manufacturing
We have mammalian production and development sites on 3 continents

Portsmouth, NH (USA)
Mammalian Cell Culture
1,500L to 20,000L cGMP

Slough (UK)
Mammalian Cell Culture
200L to 2,000L cGMP
Process R&D Services

Porriño (Spain)
Mammalian Cell Culture
4 x 10,000L cGMP

Tuas – Singapore
Mammalian Cell Culture
200L to 20,000L cGMP
Process R&D Services
Our state-of-the-art Slough, UK site is for pre- and early clinical supply

Location
- 11 miles from Heathrow airport

Footprint
- 105,000 sq. ft. (cGMP)
- 55,000 sq. ft. (PD)

Track Record
- cGMP since 1983

Notes
- Designed for multi-product concurrent manufacturing

Capacities
- 2 x 200L (Airlift)
- 1 x 500L (Stirred)
- 1 x 800L (Stirred)
- 1 x 1,000L (Single-use)
- 2 x 2,000L (Airlift)
- Associated purification suites
Our Porriño, Spain site focuses on clinical to commercial supply

Location
- 9 miles SE of Vigo, Spain
- 70 miles N of Porto, Portugal

Footprint
- 95,000 sq. ft. (cGMP)

Track Record
- cGMP since 2004

Notes
- Re-designed for multi-product concurrent manufacturing

Capacities
- 4 x 10,000L (Stirred)
- Associated purification suite
Our Portsmouth, NH, facility is for late-stage clinical and commercial supply

Location
- 60 miles N of Boston, MA

Footprint
- 350,000 sq. ft. (cGMP)

Track Record
- cGMP since 1996

Notes
- Designed for multi-product concurrent manufacturing

Capacities
- 2 x 1,500L (Perfusion)
- 3 x 5,000L (Airlift)
- 4 x 20,000L (Stirred)
- Associated purification suites
Our Tuas Biomedical Park, Singapore focuses on clinical to commercial supply

Location
- 12 miles from downtown
- 24 miles from Changi airport

Footprint
- 280,000 sq. ft. (cGMP)
- 20,000 sq. ft. (PD in construction)

Track Record
- Available in 2011

Notes
- Asia’s most advanced mammalian facility

Capacities
- 200L, 1000L, 5000L to 4 x 20,000L (Stirred)
- Associated purification suites
- Process R&D Services
We are licensed to produce numerous launched mammalian-based products

<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>Type</th>
<th>Territory licensed</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shire</td>
<td>Dynepo® (epoetin delta)</td>
<td>r Protein</td>
<td>✔</td>
<td>Slough</td>
</tr>
<tr>
<td>ImClone Systems Incorporated</td>
<td>Erbitux ® (cetuximab)</td>
<td>mAb</td>
<td>✔</td>
<td>Portsmouth</td>
</tr>
<tr>
<td>Alexion Pharmaceuticals</td>
<td>Soliris® (eculizumab)</td>
<td>mAb</td>
<td>✔</td>
<td>Portsmouth</td>
</tr>
<tr>
<td>Other</td>
<td>Confidential</td>
<td>mAb</td>
<td>✔</td>
<td>Slough</td>
</tr>
<tr>
<td>Genentech</td>
<td>Avastin® (bevacizumab)</td>
<td>mAb</td>
<td>✔</td>
<td>Porriño</td>
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<tr>
<td>Genentech</td>
<td>Rituxan® (rituximab)</td>
<td>mAb</td>
<td>✔</td>
<td>Portsmouth</td>
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<tr>
<td>Bristol-Myers Squibb</td>
<td>Orecia® (abatacept)</td>
<td>r Protein</td>
<td>✔</td>
<td>Portsmouth</td>
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<tr>
<td>GlaxoSmithKline</td>
<td>Arzerra® (ofatumumab)</td>
<td>mAb</td>
<td>✔</td>
<td>not disclosed</td>
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<tr>
<td>Lilly</td>
<td>Xigris (drotrecogin alfa (activated))</td>
<td>r Protein</td>
<td>✔</td>
<td>Portsmouth</td>
</tr>
<tr>
<td>Other</td>
<td>Confidential</td>
<td>mAb</td>
<td>✔</td>
<td>Porriño</td>
</tr>
</tbody>
</table>
Well-defined R&D and production services allow for streamlined transfers

Slough Process R&D
- Epibase™, Tripole™, AggreSolve™
- GS cell line construction
- Process development
- Process transfer
- Clinical supply
- Process optimization
- Pre-BLA validation

Porriño Production
- 10,000L

Slough Production
- Pilot 130L, 250L, 400L
- 200L, 500L, 800L
- 1,000L, 2,000L

Portsmouth Production
- 1,500L
- 5,000L
- 20,000L

Singapore Production
- 200L, 1,000L
- 5,000L, 20,000L

Well-defined R&D and production services allow for streamlined transfers...
Our process scale-up & tech transfer support leave little to chance

**Expertise**
- Fermentation, primary recovery, purification
- Transfer between stirred and airlift bioreactors

**Tech Transfer**
- Lonza development to Lonza cGMP sites
- From customer to Lonza (reciprocal on-plant visits)

**Pilot Scale Evaluation**
- 400L stirred tank, 130L airlift and disposable bioreactors with associated purification technology

**Full Support**
- Provision of material for toxicology studies
- Creation of process descriptions for cGMP production
- On-plant technical support
Our Slough, UK site is also home to mammalian development services

**Technologies**
- The GS Gene Expression System™
- Potelligent® CHOK1SV
- Epibase™

**Services**
- Cell line & cell bank creation
- Full cell culture & purification process development
- Product stability studies
- Product characterization
- Process optimization
- Preformulation studies

**Summary**
- Purpose-built, state-of-the-art laboratories located over 3 sites (Slough, Winnersh and Cambridge)
- Over 250 scientists
- 82 projects progressed in 2010
The GS System™ is a widely accepted, industry-leading expression system

Industry-Leading Expression System
- Owned and licensed by Lonza
- A mammalian gene expression system
- For therapeutic proteins and monoclonal antibodies
- GS-CHO and GS-NS0 cell lines

Widely Accepted
- Over 100 companies, 75 academic institutions
- Over 230 products in the clinic
- 100s of high-yielding cell lines created (last 15 years)
Using the GS System™ is proven to improve yields and speed

<table>
<thead>
<tr>
<th>High-yielding cell lines</th>
<th>Up to 9.6 g/L GS-CHO 1.9g/L GS-NS0 in chemically defined, animal component-free medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speed</td>
<td>No need for rounds of gene amplification</td>
</tr>
<tr>
<td>Scale Up</td>
<td>Predictable (1 to 20,000L currently)</td>
</tr>
<tr>
<td>Regulatory Acceptance</td>
<td>9 licensed products: Zenapax® (Roche), Synagis® (MedImmune), Soliris® (Alexion), &amp; 5 mAbs, 1 protein</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Complete support package</td>
</tr>
</tbody>
</table>
The majority of products will achieve more than 3g/L using the GS System™

Product concentrations for GS-CHO cell lines making different antibodies in Lonza’s cGMP manufacturing bioreactors (200 -10,000 L)

The majority of products will achieve more than 3g/L using the GS System™

Product concentrations for GS-CHO cell lines making different antibodies in Lonza’s cGMP manufacturing bioreactors (200 -10,000 L)

- The majority of products will achieve more than 3g/L using the GS System™.
- Data for each cell line are mean values from \( n \geq 1 \) runs. Harvested no later than 15 days after inoculation.

Number of Cell Lines (Each Making a Different Product) vs. Product Concentration (g/L)
Lonza’s GS cell line constructions give you what you need when you need it

<table>
<thead>
<tr>
<th>GS Cell Line Construction (CLC)</th>
<th>Yield</th>
<th>Phase(s)</th>
<th>Timetable (months)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proof of Concept from pooled transfectants</td>
<td></td>
<td>preclinical</td>
<td>4</td>
</tr>
<tr>
<td>Fast Track Express Uncloned cell line</td>
<td>up to 4g/L</td>
<td>early clinical</td>
<td>11</td>
</tr>
<tr>
<td>Fast Track Uncloned cell line</td>
<td>up to 5.5g/L</td>
<td>early clinical</td>
<td>12</td>
</tr>
<tr>
<td>One-Step Clonal cell line</td>
<td>up to 5.5g/L</td>
<td>all &amp; in-market</td>
<td>13</td>
</tr>
<tr>
<td>Two-Step Clonal cell line</td>
<td>up to 5.5g/L</td>
<td>all &amp; in-market</td>
<td>18</td>
</tr>
</tbody>
</table>

*Period from receipt of DNA to delivery of cGMP bulk product in quarantine
Applied Protein Services: Core Technologies

Algonomics Epibase™ & Epibase IV™
- Computer-based and cellular immunoprofiling for lead selection, lead comparison, optimization and surveillance

Tripole™ Protein Engineering
- Technology platform for protein structure analysis, modeling, engineering, deimmunization and antibody optimization

Humanization
- Sequence modification of non-human proteins via CDR grafting

Applied Protein Services is a platform of immunogenicity, stability and protein engineering services
**Light Path™**: streamlined custom material supply for discovery to early development

- Leverage Lonza’s proven technology platforms & expertise to meet your exact early development needs in a lean, cost effective and speedy manner
- Complete gene to GMP production service offerings for both microbial & mammalian technology
- Partner with Lonza early and be on the road to a marketable product
Meet all your discovery, pre-clinical & phase 1 material needs with Light Path™

Drug Discovery

Preclinical Development

Phase I

Light Path™ Discovery

1mg – 500mg, non GMP in 6 to 10 weeks

Light Path™ Development

1 - 100 grams, non-GMP in 4 to 8 months

1g - 1000 grams, GMP in 3 to 6 additional months

* starting from gene sequence, timeline guidance includes gene synthesis.
Mammalian Light Path™ Discovery for custom milligram material supply (non-GMP)

- Product expression using Lonza’s proprietary GS Gene Expression System™
- Option to perform vector construction suitable for future stable cell line development
- Option to apply your specific affinity chromatography step
- Option to monitor endotoxin levels and include additional purification steps
- Material supply for multiple product candidates
Mammalian Light Path™ Development for pre-clinical through to your IND

Starting from a gene sequence:

- **Cell Line Construction**
- **Streamlined PD**
- **non-GMP Pilot Supply Option (1-100g)**
- **Pre-production Activities**
- **GMP Production (10g – 1000g)**

Option for mg supply via Light Path™ Discovery
## Compare Mammalian Light Path™ Development to Lonza’s standard GMP programs

<table>
<thead>
<tr>
<th>Service</th>
<th>Standard</th>
<th>Light Path</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cell line Construction</strong></td>
<td>- Options for development of unclonal or clonal cell lines</td>
<td>- Options for development of transfectant pool, unclonal or clonal cell line</td>
</tr>
<tr>
<td></td>
<td>- Vector construction, transfection and multiple rounds of cell line screening where applicable</td>
<td>- Vector construction, transfection and limited rounds of cell line screening where applicable</td>
</tr>
<tr>
<td></td>
<td>- Cell line stability study on three candidate cell lines</td>
<td>- No cell line stability study unless requested</td>
</tr>
<tr>
<td></td>
<td>- Supply of up to 5 mg of Protein A purified product from top 9 selected cell lines</td>
<td>- Supply of up to 5 mg of Protein A purified product from top 9 selected cell lines</td>
</tr>
<tr>
<td><strong>Upstream Development</strong></td>
<td>- Application and evaluation of Lonza’s platform upstream process</td>
<td>- Application of Lonza’s platform upstream process</td>
</tr>
<tr>
<td></td>
<td>- Performance of 2x10L scale and material supply for purification process development</td>
<td>- Performance of 2x10L lab scale for purpose of material supply for purification evaluation only</td>
</tr>
<tr>
<td></td>
<td>- Material supply of up to 5 mg Protein A purified product for animal efficacy studies</td>
<td></td>
</tr>
</tbody>
</table>
### Service

<table>
<thead>
<tr>
<th>Standard</th>
<th>Light Path</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Downstream Development</strong></td>
<td></td>
</tr>
</tbody>
</table>
| - Application and evaluation of all steps of Lonza’s platform downstream process  
- Intermediate product stability study | - Assumes product is a monoclonal antibody of subclass IgG1, 2 or 4 with pI>8 and aggregate levels of <10  
- Evaluation of limited steps of Lonza’s platform downstream process- can we name which ones?  
- No intermediate product stability study |
| **Analytical Development** |  |
| - Evaluation of Lonza’s Protein A HPLC and a range of platform assays | - Evaluation of limited platform assays ?? |
| **Pilot Production** |  |
| - Non-GMP runs at 130L, 250L or 400L scale (tox material supply) | - No non-GMP pilot run unless requested |
| **GMP Production** |  |
| - Any scale | - 200L, 500L, 800L, 1000L or 2000L |
Decide if Mammalian Light Path™ Development is right for you

- Take the Light Path™ when your focus is strictly on filing an IND
- If certain budgetary restrictions would require scope limitations, then Lonza will focus on only necessary activities
- Light Path™ requires an in-depth discussion with Lonza to agree in partnership on how to best design your program. Lonza will highlight areas where potential challenges may arise that could require scope change.
- Leverage of Lonza’s proven GS expression system™ and processes development platforms to generate an IND enabling
Development Services: Cell Culture Process Development

Cell Line Development
- GS-CHO, GS-NS0 cell line construction
- Chemically defined, animal component-free cell culture medium & feed development
- 100s of high-yielding cell lines created in house
- Cell bank creation
- Dual-site storage of cGMP cell banks

Rapid Process Evaluation
- GS-NS0, GS-CHO, dhfr CHO, hybridoma, human cell
- Process transfer to pilot or manufacturing scale
- Stirred, airlift, disposable bioreactor configurations
- 100s of processes developed over 30 years
We are experts at cell line transfers for development and manufacturing

Process Transfer to Lonza* (GS, non-GS)

Transfer of cell line for
- process development
- scale-up
- transfer to cGMP manufacturing

12 months

Transfer of cell line and process for
- scale-up
- transfer to cGMP manufacturing

10 months

*Start of transfer of material to delivery of cGMP bulk product in quarantine
Development Services: Supply from Pooled Transfections

Quick, Stable Supply

- From a pool of GS CHO transfectants; delivery in 4 months
- Combines harvest concentrations of the stable expression format with the speed of the transient expression format
- Chemically-defined, animal component-free process for rapid production in CHO cells (e.g. up to 50g of antibodies)

Applications

- Formulation development, animal models
Development Services: Purification

Purification Development

- Experienced in IgG₁/₂/₃/₄, IgM, antibody fragment and fusion protein purification
- cGMP processes developed and scaled up for over 100 different mAbs
- Processes also developed for recombinant proteins and hormones

Rapid Process Evaluation

- Platform process available for IgG antibodies
- Includes specific steps for virus removal and inactivation
- Process transfer to pilot or manufacturing scale
Development Services: Analytical Development & QC

A Full Range

- Development and application of analytical methods for all stages of process development

Assay Method Expertise

- Process monitoring and impurity assays
- Product characterization and comparability
- Product stability
- Method validation
- QC release testing
- Assay validation
- Environmental monitoring
Development Services: Analytical Development & QC

Generic Methods Assays
- Consistent with requirements of ICH and pharmacopoeias
- Standard test methods (electrophoresis/HPLC)
- Product and process related impurities including host cell protein

Method Transfers
- Extensive experience of transfers, qualifications and validations
- Product-specific activity and bioassays
Development Services: Analytical Development & QC

Product Characterization
- Number of additional complex methods
- Including mass spectrometry, glycosylation and secondary structure methods

Stability Studies
- Liquid formulation development
- Stability studies to ICH
- Accelerated studies and characterisation of degradation products
Development Services: Further Development / Optimization

- Typically for late-phase clinical and in-market supply
- Increase productivity, process robustness and throughput
- Medium and feed process development
- Physicochemical environment evaluation
- Productivity strategies for CHO, NS0 and hybridoma protein-free and serum-free fermentation processes
- Product specific improvement of platform processes
- Further development of downstream processes for large-scale operation
Development Services: Process Validation

Experience
- Fermentation, purification and assay validation
- For late phase clinical and in-market supply
- Supported 9 license applications in the last 5 years

Services
- Process limits evaluations, consistency and equivalence studies, viral clearance
- Collaborate with production groups on design of studies
- Process-specific data to support license applications
- Regulatory support
Why Outsource with Lonza?

**Partnership Mentality**
- We are committed to ensuring your success
- Available for long-term strategic, pipeline agreements

**Experience = Reliability**
- Proven track record
- Technical & project management excellence
- Quality Assurance & Regulatory expertise

**Lower Risk, Remain Flexible, Stay Focused**
- Avoid investment in potentially unused facilities
- Improve flexibility and speed to market
- Focus your resources on your core capabilities
Mammalian Backup Slides
Lonza’s single-use bioreactors are a viable bioreactor alternative

Non-disposable Shell
- Stainless steel container
- Heating electrical jacket and control
- Temperature sensor
- Drive motor and control for impeller rotation
- Drive shaft
- The electric heater
Single-use bioreactors are flexible, effective and reliable

**Single-Use Bag**
- Impeller and Sparger
- Connectors for probe/shot additions
- Various tubing for media/inoculum/feed addition
- Inlet and outlet gas filters
- Sample line, temperature probe inlet

**GMP Requirements**
- Disposable Bag
  - Supplied gamma-irradiated; USP Class VI material
  - Animal-free product contact components
  - Bag film used in U.S.: extractable and leachables studies available
Using the GS System™ leads to higher product concentrations

Product concentrations for GS-CHO cell lines making different antibodies in Lonza’s cGMP manufacturing bioreactors
Now a multi-product plant, our Porriño site has a strong inspection history

<table>
<thead>
<tr>
<th>Porriño, Spain</th>
<th>Agency</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2009</td>
<td>AEMPS</td>
<td>GMP / Major changes</td>
</tr>
<tr>
<td>October 2008</td>
<td>Russian Agency</td>
<td>Specific testing in QC Lab</td>
</tr>
<tr>
<td>April 2006</td>
<td>AEMPS</td>
<td>GMP / Major changes</td>
</tr>
<tr>
<td>September 2005</td>
<td>FDA</td>
<td>PAI</td>
</tr>
<tr>
<td>August 2004</td>
<td>AEMPS (Spanish Agency)</td>
<td>GMP</td>
</tr>
</tbody>
</table>

⭐5 Regulatory Inspections Since 2004⭐ 1 Product Licensed from Porriño
### Our Slough site has a long history of successful quality inspections

<table>
<thead>
<tr>
<th>Slough, UK</th>
<th>Scale</th>
<th>Agency</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2009</td>
<td>2K</td>
<td>FDA</td>
<td>PAI</td>
</tr>
<tr>
<td>March-April 2009</td>
<td>5K</td>
<td>MHRA</td>
<td>General site / GMP inspection for cell bank and DSP</td>
</tr>
<tr>
<td>March 2009</td>
<td>n/a</td>
<td>MHRA</td>
<td>PAI (Winnersh Labs only)</td>
</tr>
<tr>
<td>September 2007</td>
<td>200L</td>
<td>PMDA</td>
<td>Inspection</td>
</tr>
<tr>
<td>December 2006</td>
<td>200L</td>
<td>PMDA</td>
<td>PAI</td>
</tr>
<tr>
<td>July 2006</td>
<td>200L</td>
<td>MHRA</td>
<td>PAI</td>
</tr>
<tr>
<td>June 2006</td>
<td>2K</td>
<td>MHRA</td>
<td>PAI</td>
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<tr>
<td>August 2002</td>
<td>Various</td>
<td>FDA</td>
<td>Biennial</td>
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<tr>
<td>March 2000</td>
<td>200L</td>
<td>FDA</td>
<td>PAI</td>
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<tr>
<td>January 2000</td>
<td>Various</td>
<td>FDA</td>
<td>Biennial</td>
</tr>
<tr>
<td>September 1998</td>
<td>Various</td>
<td>FDA</td>
<td>Biennial</td>
</tr>
<tr>
<td>January 1996</td>
<td>Various</td>
<td>FDA</td>
<td>Biennial</td>
</tr>
<tr>
<td>June 1995</td>
<td>200L</td>
<td>MCA</td>
<td>Biennial</td>
</tr>
</tbody>
</table>

★ 13 Regulatory Inspections Since 1995 ★ 16 GMP Customer Audits / Yr ★ 3 Products Licensed from Slough
Our Portsmouth site has a long history of successful quality inspections (1/2)

<table>
<thead>
<tr>
<th>Portsmouth, NH (USA)</th>
<th>Scale</th>
<th>Agency</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2009</td>
<td>1.5K</td>
<td>Mexican MOH</td>
<td>GMP</td>
</tr>
<tr>
<td>September 2007</td>
<td>1.5K, 5K, 20K</td>
<td>FDA / Team Biologics</td>
<td>GMP</td>
</tr>
<tr>
<td>June 2007</td>
<td>1.5K, 5K, 20K</td>
<td>EMEA / UK</td>
<td>PAI and GMP</td>
</tr>
<tr>
<td>June 2007</td>
<td>1.5K, 20K</td>
<td>Brazilian MOH / ANVISA</td>
<td>PAI</td>
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<tr>
<td>May 2007</td>
<td>20K</td>
<td>Health Canada</td>
<td>PAI</td>
</tr>
<tr>
<td>January 2007</td>
<td>5K</td>
<td>FDA</td>
<td>PAI</td>
</tr>
<tr>
<td>November 2006</td>
<td>1.5K</td>
<td>Mexican MOH</td>
<td>GMP</td>
</tr>
<tr>
<td>September 2006</td>
<td>20K</td>
<td>PMDA / Japan</td>
<td>PAI</td>
</tr>
<tr>
<td>July 2006</td>
<td>20K</td>
<td>EMEA / Italy</td>
<td>PAI</td>
</tr>
<tr>
<td>June 2006</td>
<td>1.5K</td>
<td>Mexican MOH</td>
<td>GMP</td>
</tr>
<tr>
<td>March 2006</td>
<td>20K</td>
<td>FDA</td>
<td>PAI</td>
</tr>
</tbody>
</table>

- ★ 23 Regulatory Inspections since 2001  
- ★ 10 Client Audits / Yr  
- ★ 6 Products Licensed from Portsmouth
Our Portsmouth site has a long history of successful quality inspections (2/2)

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>December 2005</td>
<td>1.5K</td>
<td>EMEA / Germany</td>
<td>GMP</td>
</tr>
<tr>
<td>November 2005</td>
<td>20K</td>
<td>EMEA / Germany</td>
<td>PAI</td>
</tr>
<tr>
<td>July 2005</td>
<td>20K</td>
<td>FDA</td>
<td>PAI</td>
</tr>
<tr>
<td>October 2004</td>
<td>1.5K</td>
<td>Mexican MOH</td>
<td>GMP</td>
</tr>
<tr>
<td>November 2003</td>
<td>5K</td>
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★ 23 Regulatory Inspections since 2001 ★ 10 Client Audits / Yr ★ 6 Products Licensed from Portsmouth