

The Art of Juggling: Internal Users versus External Clients in a NATA Accredited SRL

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What is NATA?

Why seek accreditation?

National
Association
Testing
Authorities



Increasingly
required for clinical
trials



Confidence to
users and clients



Data quality &
integrity



Flow Cytometry & Imaging Facility

Who are we?
QIMR Berghofer,
Brisbane



What do we have?



Instrumentation

Analysers:

- ▶ 2 x Cytex Auroras
- ▶ 4 x BD Fortessas
- ▶ 1x AMNIS
- ▶ 1x ATTUNE

Cell Sorting:

- ▶ ThermoFisher Bigfoot Spectral cell sorter
- ▶ BD FACS Aria IIIu
- ▶ Beckman Coulter MoFlo XDP

Services Provided

“Normal” SRL activities:

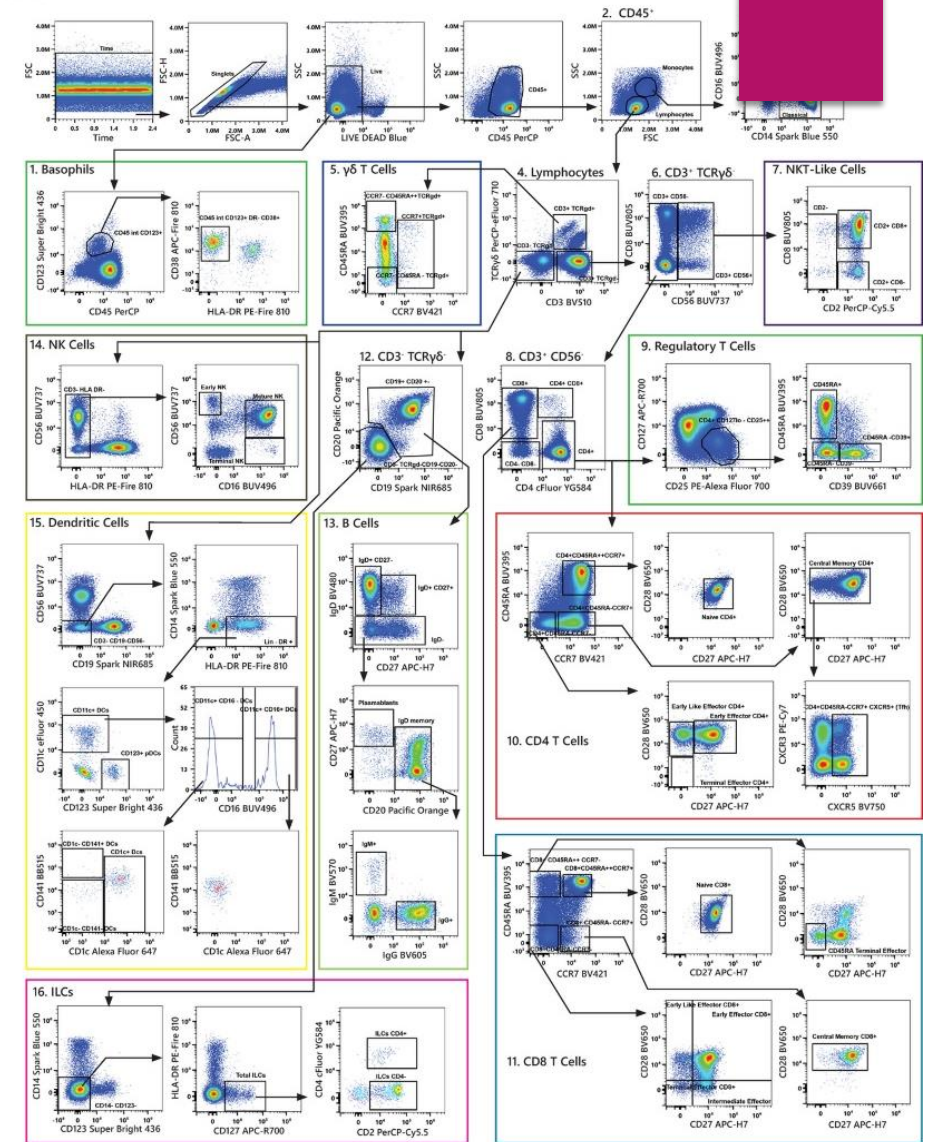
- Training & Education
- Assisting internal researchers
- Cell sorting

“Extended” activities:

- Full service provision for internal researchers
- Contract clinical trial work
- Facility staff all have a PhD and have had active research careers

Full Service Provision

1. Panel design
2. Panel validation and optimization
3. Sample preparation & staining
4. Sample acquisition
5. Data Analysis



Our Scope of Accreditation: ISO/IEC 17025

- ▶ **PROCESS:** Immunophenotyping by flow cytometry.
 - ▶ **Any** flow assay on **any** instrument

QIMR Berghofer Scientific Services

ISO/IEC 17025 (2017)

Healthcare, Pharmaceutical and Media Products

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE
Analysis in support of clinical trials and/or pre-clinical studies	Animal biological samples; Human biological samples	Cell characterisation, identification and isolation	Flow cytometry - Immunophenotyping

JUGGLING



Available Time

Challenges

- ▶ Time to perform lab work
- ▶ Scientific reading needed for the work
- ▶ Meetings often are more frequent – need more preparation (minutes etc.)
- ▶ Report writing
- ▶ Deadlines are not as fluid

Addressing the Challenges

- ▶ QMS streamlines processes
- ▶ Templates
- ▶ Some facility staff remain largely dedicated to internal research usage
- ▶ Automated QMS system coming on board!



Staffing

Challenges

- ▶ More specific training for each project – not necessarily just more hands
- ▶ Staffing needs for unknown external clients are harder to predict

Addressing the Challenge

- ▶ Dedicated Quality Co-Ordinator
- ▶ Dedicated Quality Manager
- ▶ Institute 'buy in' means more staff to be hired



Shared Resource Lab = Shared Space

Challenges

- Shared main lab space, instruments, and instrument reagents
- Internal users are not required to be familiar with our QMS

Addressing the Challenge

- Restricted access to our clinical room
 - Sample preparation
 - Reagent storage
- High training standards
- Facility staff oversight



Shared Resource Lab = Shared Instruments

Challenges

- Shared instruments

Addressing the Challenge

- CAPA process: monitoring of equipment performance is proactive = less down time
- Quality Assurance Program (RCPAQAP)
- QC checks are performed immediately prior to accredited use of an instrument



Summary of benefits of becoming NATA accredited



Improved our quality of service



Full service provision for internals is available



Increased staff competency and training



Rewarding to see results



Visibility of service



Closer to the 'bedside'



Thank you!

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