Emission ProFiler®2005 SPRI Calculation and Reporting Software Targets NJDEP Pilot Plant, R&D General Permit Compliance

Paper # 582

Elizabeth A. Dirnfeld and Frederick R. Kohler

Schering-Plough Research Institute, 1011 Morris Avenue, Union, NJ 07083

John F. Takacs

HighPoint Software Services, Inc., P.O. Box 874, Westminster, MA 01473

ABSTRACT

Emission ProFiler (EP) was designed for pharmaceutical batch processing applications. Emission ProFiler incorporates an innovative and customized approach to air quality and permit compliance management. EP provides a platform that facilitates rapid modeling of sequential unit operations enabling a faster turn-around time for environmental approval of new / modified research and development processes.

Emission ProFiler was developed to address the requirements of both the Pilot Plant Permit and the new General Permit for Research & Development issued by the New Jersey Department of Environmental Protection (NJDEP).

Emission ProFiler is a Windows-based system that calculates, tracks and reports emissions in the kilo to pilot plant-scale batch production of pharmaceutical products. EP is based on US EPA Office of Quality Planning and Standards (OAQPS) calculation methods. EP maintains all individual unit operations by experiment for each product in the system. Control devices are also tracked in the system to calculate pre- and post-control emissions. To verify the calculations, a detailed step-by-step printout of each unit operation's calculations is available with references in the calculations to the appropriate US EPA equation. The reports in the system are used to meet state, federal and internal reporting requirements.

Although primarily an air permit compliance tool, EP has the additional ability to simultaneously track information on wastewaster and hazardous waste production from pharmaceutical processes for use in other regulatory systems.

INTRODUCTION

Research & Development (R&D) pharmaceutical batch processing of active pharmaceutical ingredients (API) in New Jersey provides a compliance challenge to engineers, who are often held accountable for short-term health effect (SHE) impacts. On one hand, regulatory requirements of NJDEP Air Permits need to be met with professional competence and thoroughly documented as part of an overall environmental management plan. On the other hand, an expanding, diverse and rapidly evolving pipeline necessitates a speedy and highly-focused environmental assessment of batch processes heading for plant scale-up. The key to meeting both goals lies in the engineering toolbox. Unlike off-the-shelf software, Emission ProFiler does not attempt to meet every environmental need, confuse the user with a multitude

of overlapping windows, or require lengthy set-up better meant for manufacturing facilities. Its simplicity lends itself to modeling of sequential unit operations within a smart and logical framework. With a batch recipe in one hand and Emission ProFiler in the other, an engineer can weed out troublesome operations, apply control device removals, determine emission rate compliance, and keep a tab on HAP and other targeted pollutants. Reports can be customized by the user for both regulatory purposes and internal tracking.

Emission ProFiler SYSTEM

The Emission ProFiler system is a Windows-based program developed in Microsoft's Visual Basic to calculate, track and report VOC and HAP emissions in the batch production of pharmaceutical products. Emission ProFiler is based on US EPA Office of Quality Planning and Standards (OAQPS) calculation methods. ^{1,2,3} EP maintains all individual unit operations for each experiment in the system. Control devices are also tracked in the system to calculate pre- and post-control emissions. To verify the calculations, a detailed step-by-step printout of each unit operation's calculations is available with references in the calculations to the appropriate US EPA equation. The reports in the system are used to meet state, federal and internal reporting requirements.

Figure 1. Emission ProFiler Start-up Screen.



Figure 2 shows the main toolbar in Emission ProFiler.

Figure 2. Emission ProFiler Main Toolbar.

📲 Schering-Pla	ugh Emission Pri	riler								_ 8
File Edit Option	ns Admin Windo	w Help								
Batches	Reports	Chenicals	Equipment	Buildings	Unit Types	Emission Points	Unit Operations	Fugitive Factors	Activity Desc	Condenser Types
Emission Limits	Default Rates	Ext								

In Emission ProFiler users enter batch product information, produce reports or maintain support databases. The support databases contain information that is used throughout the system. Emission ProFiler's support databases are as follows:

- Chemicals
- Equipment
- Buildings
- Unit Types
- Emission Points
- Unit Operations
- Fugitive Factors
- Activity Description
- Condenser Types
- Emission Units
- Default Rates

Each support databases is a separate button in the Emission ProFiler toolbar. An example of the support databases for Unit Operations is shown in Figure 3. The Unit Operations table includes information on the operation type, OAQPS equation type, required input parameters and default input parameters.

fi Uni	t Operati	ions - (Cha	rging]								_ 0
	rit Opera A Operatio								-Nomber (OlVessels-	Controls
	harging					□ Add	as Individu	al Operations	c		Iop
											Previous
ΙH	Step #	Vessel	Equation - BAGPS 1994	Equation - 0.4QPS 1978	Steps Equation - MACT	Equation - 0	he	Point Source	Fugilize 0	Continuous Sweep	Next
Þ		Vessel 1		Filing	Vapor Displacement			E.	P	M	Bottom
											Bave
											Egit
											Add
											Delete
					Parameters						
	Step #	Soft Order		Field Name		Jt Value Use Min		Min Value Ma	k Value Calo	ulated Scaling	Find
	1	1	Charge Rate (gal/min)	hi nate gal pa		V		0 0			
	1	2	Charge Volume (L)	M_volume_Ret		म ज		0 0	F	<u>प</u>	Close
	1	3	Vessel Temperature ("C)	vessel_temper	alure_deg_c	M	E	-100 200			

The maneuvering controls in Figure 3 are similar to those used throughout EP. The user can move through the records in the database with the Top, Previous, Next or Bottom button or use the Find button to display a list of all records in the database (Figure 4). To modify existing data the user selects the Edit button. The Add button allows the user to enter a new unit operation type. After editing or adding new information, the user presses the Save button to save all of the new information. The Delete button allows the user to remove records.

		Find Unit Operation:		mbe
_				
_		Unit Operation	Number of Vessels	
	•	Adjustment	1	
		Agitate	1	
² S 19		Air Drying	1	ive
		Atmospheric Distillation	2	1
		Centrifuge	1	
		Charge By Pumping	1	
		Charge Solids	1	
		Charge Solids2	1	
		Charge via Feedbottle	2	
		Charging	1	
		Combo	1	
_		Combo2	1	
		Cooling	1	
		Depressurization	1	» C
/min)		Empty Vessel Purging	1	
_)		Evacuation	1	
ure (*		Filling	1	
		Fugitives Only	1	
		Gas Evolution	1	
		Gas Sparging	1	
		Gas Sweep	1	
		Gravity Charging	1	
		Heating	1	
	10	Heating Under Vacuum		
			1	
		<u>O</u> k <u>C</u> ancel		
ļ				

Figure 4. Unit Operations Find Screen.

The entry of batch experiment information is in the Batches module. Pressing the Batches button displays the Load Experiment screen shown in Figure 5. This screen allows the user to select a year to work with. When a year is selected (highlighted), all of the existing experiments in the selected year are displayed in the bottom grid. In the experiments grid, the user can select an experiment to work with or add/remove experiments.

_		_	lough Emission Pi											
File	Edit	Opt	tions Admin Wind	1				1						
	Batches	s	Reports	Ch	emicals	Equipn	nent	Buildings	L	Jnit Types	Emis	sion Points	Unit Operat	ions
Emi	ission Li	imits	Default Rates		Exit									
ii L	oad Ex	(pe	riment											
		_												1
						Yea						<u></u> p	pen	
			Year				Desc	ription				Calcul	late All	
		▶	2006	EP TES										
		-	2005 2004 Test	EP TES EP TES							-	C <u>l</u> o	ose	
			2004 16%	EF IES	1 2004									
												Change	gn Dates	
												Campai	gribales	
											V			
			New Year		Сору Үе	ear	Rem	ioveYear	E	Edit Year				
						Experin	nents							
			Experiment ID				eriment N	ame		Date				
		•	2006 TEST		2006 TES				9/	18/2006				
			2006 TEST 2		Test 2				9/	18/2006				
			80 L		80L				9/	18/2006				
			Unload		Unload Te	est			9/	18/2006				
					-									
			New Experiment	Cop	y Experir	ment F	Kemove	e Experiment	Ed	lit Experime	ent			

Figure 5. Batch Records Year / Experiment Selection Screen.

After selecting an experiment to work with, the user presses the Open button. Opening an experiment (Figure 6) displays the campaigns screen. The experiment information consists of a flip card that supplies detailed information on the campaign, individual batch unit operations, chemicals used in the process, control devices and emissions information at the batch record level. Figure 6 shows the campaigns flip card. On the campaigns flip card the experiment start and stop time is recorded along with default

information for any process condensers present and a data field for adding specific comments about the experiment campaign.

Figure 6	Campaigns Screen	for a Selected	Experiment
I Iguie 0.	Cumpargns bereen	101 a beleeted	Experiment.

Hatch Records - [2006] - [2006 TEST 1] - [2006 TEST 1]	_10
Campaigns Batch Operation Data Chemicals Control Devices Emissions Emissions Summary Change Equipment	
Compaigo	Controls
Carpaign Narse	Iop
2006 TEST 1	Previous
Start Date End Date Default Sweep Rate (sch)	Next
Connerts	Eottam
Default Vezzel 1 Process Condenser	Seve
Condenser	Edit
TagNumber	Add
Y I I I I I I I I I I I I I I I I I I I	Copy
Temperature (*C)	Block Repeat
	Defete
	Find
Default Vessel 2 Process Condenser	
Process Condenser	Re-Order Ops
	Re-Calc Campaign
T og Number	Select Experiment
Temperature (*C)	Vapor/Boil Calc
<u> </u>	Close

The Copy button at the campaign level allows the user to a make a complete copy of the selected campaign including all batch record steps, chemicals and control devices.

Selecting the Batch flip card (Figure 7) displays a list of the individual unit operations that make up the entire batch record cycle. To add a new step to this batch record, the user presses the Add button. The Copy button will copy an existing batch record with all of its information and add it as a new record at the end of the batch record cycle. There is also a block repeat function that allows selecting one or more unit operations and copying them as many times as necessary. If the order of the unit operations in the batch record needs to be changed, the operations can be rearranged using the Re-Order Ops button.

To look at the detailed information about an individual unit operation in the batch record, the user clicks on a record in the grid. The selected record then becomes highlighted. Once a record is highlighted, the user can look at detailed input and emissions information for that unit operation on the following flip cards.

campaigns	DetCh	Operatio	n Data Chemicals	Control Device	Emis	ssions	Emissions	summary	Change	Equipment		
				Ope	tions							Controls
Operation #	Vescel 1	Vessel 2	Unit Operation		el 1 Va ess Pr moer Cor	essel 1 Vocess nd. Tag	Vessel 1 Process Cond. Temp (*C)	Vessel 2 Process Condenser	Vessel 2 Process Cond. Tag	Vessel 2 Process Cond. Temp (*C)	Control	Top Previous
► 1	R-300A		Charging	F	PC-1		15	Г		D	R	
2	R-300A		Heating	1			0			0	R	Next
	R-3004		Pressuization	1			0			0	R	Bottom
4	R-3004		Evacuation	1			0	Г		0	4	Seve
												Edit
												E <u>dit</u> Add
												∆dd <u>C</u> opy
												∆dd <u>C</u> opy
												Add Copy Block Reper
												Add Copy Block Repea Delete Find
												Add Dopy Block Repea
												Add Dopy Block Repec Delete Find Re-Order Op Re-Calc Campo
												Add Dopy Block Repea Delete Find Re-Order Op

Figure 7. Batch Record Grid

Selecting the Operation Data flip card (Figure 8) displays the input data for the individual unit operation. The unit operation input data fields will vary depending on the required information for a unit operation. Figure 8 displays an example for a vessel Charging operation. The required input fields are vessel charge rate and the exit temperature from the vessel. The amount of material charged to the vessel is determined on the Chemicals flip card. On the Operation Data screen the user is also able to indicate if a process condenser is present and if a continuous gas sweep takes place during this unit operation. The Steps grid at the top part of the screen, shows unit operations that composed this step. Some unit operations can have more than one step. In the case of a Charging operation, there is only one step. In this grid the OAQPS equation set used is documented along with information about a continuous gas sweep on the operation step.

_	esation Numb	er Vez	sel 1	Vessel 2		Unit Operation	Controls
1			100A			Charging	Iop
Inpo						,	Brevious
	Step #	Vestel	Equation Name	Equation Set	Continuous Sweep	Sweep Rate (soft) Emission Point	Next
Þ	1 8	R-300A	Filing	0.4QPS 1994	Yes	5	Bottom
							Save
							Egit
							Add
- P	atameters			1		300A Process Condenser	Copy
	Step #	Equals			-	Process Cond. Tag Number	
	▶ 1 1	Filling	Charge Rate (gal/m Charge Volume (L)	160.00		Condenser PC-15	Block Repeat
	1	Filing	Vessel Temperature		_	Cond. Temp (*C)	Delete
		1	Turninterperate			15	
					-Ve	siel 2 Process Condenser	Fjind
						Cond. Tea Number	Re-Order Ops
						Process Condenser	
							Re-Calo Campaig
						Cond. Temp ('C)	
						0	Select Experimen

Figure 8. Unit Operation Op Data Input Screen.

Selecting the Chemicals flip card (Figure 9) displays the screen that shows the chemicals used in the selected unit operation. The top grid on this screen shows the contents of the vessel that is the results of any previous unit operation along with the activity in this unit operation. The Activity Summary grid at the bottom of the page, shows the chemical transactions for this specific unit operation.

Version Contention Distriction Contention Name Addrewindtion State Quartity Method Method Quartity State State Book Addivity Summary Devices Periode Quartity Priod Addivity Summary Device Periode Periode Device Periode Periode Periode Periode Periode Periode Periode Periode Periode P		npaigns Batch Operation Data Chemicals C	onour perices Emis	anna Em	residine admi	nary onar	ige Equipme	" 	Controls
State Observice Observice <thobservice< th=""> <thobservice< th=""></thobservice<></thobservice<>	-		Ments R-300A (42.27 Gallo	ns / 160.00 Li	lers)				-
3004 Methanol MEOH LIQUID 42.272 160.0 125.72 100.0 100.0 Next Bottom Seve Egit Addd Addd Seve Egit Addd Addd Seve Egit Addd Seve Seve Egit Addd Seve Seve Seve Seve Seve Seve Seve S	ł		Abbreviation .	Rinte	0.0.0			*	Tob
Activity Summary		Contraction of the contraction o							Brevious
Activity Summary pt Vessel Acti Chemical Name Quantity Units Activity Description R-300A AL Methand TB0.0 LITERS RAW MATERIAL								_	Next
Activity Summary									Bottom
Activity Summary p									Seve
Activity Summary									E <u>d</u> it
Activity Sunnary p Activity Sunnary p Activity Sunnary p Activity Description Taget Step Taget Vessel Find Find Re-Order Ops Re-Order Ops Re-Order Ops Select Experiment									Add
Activity Summary op # Vessel Acti Chemical Name Quarky Units Activity Description Target Step Target Vessel Find R-300A AL Methanol 160.0 LITERS RAW/ MATERIAL Performance Find Re-Order Ops Re-Order Ops Re-Order Ops Re-Order Ops Re-Order Ops Re-Order Ops Re-Order Ops Select Experiment Select Experiment Select Experiment Select Experiment Select Experiment									<u>С</u> ору
Ip # Vessel Acts Chemical Name Quarty Units Activity Description Target Step Target Vessel R-300A AL Methanol 160.0 LITERS RAW MATERIAL Find									Block Repeat
R-300A 4L Methanol 160.0 LITERS RAW MATERIAL Find Re-Order Ops Re-Order Ops Re-Order Company Select Experiment	T	Press R. Marcoll, J. M. Pharmark Marcol		Laws				1) for a state	Delete
Re-Celo Campaign Select Experiment	ł					1.05	get step 1 args	(Vessel	Find
Select Experiment									Re-Order Ops
									Re-Calc Campaig
Vapor/Boil Calc									Select Experiment
									Vapot/Boil Calc

Figure 9. Unit Operation Chemical Usage Screen.

To add or remove a chemical in the Activity Summary section the buttons on the lower half of the screen are used. Selecting New, Remove or Edit displays the chemical activity screen (Figure 10).

Step / Vessel	Chemical					
Step Number Vessel						
1 • R-300A	Drawical Name	Abberviation	VDC	EHS	HAP	CADA 212
	Maleic Anhydride	ADDREVIDION		EHS	PAP	SARA 313
Equation Name	Malic acid. DL-		-		-	
Filing	Maloric Acid			<u> </u>	-	
	Mandelic Acid. F		<u> </u>	<u> </u>	-	
Activity	Manganese Sulfate		1-	<u> </u>	<u> </u>	- <u>-</u>
C Addian C Tamle	Meito Sango Lipase OF 360		1 -	t in	1	
C Renoval C Off-Gao	Mercaptoethanol, 2-		1 -	1 F	i i i	
	Mercuic Acetate		1 F	L F	Ē	
Addition Type	Meul Dioide		Τ́Γ	Τ <u>Γ</u>	Ē	
	MethIodine	MEI	2	t in	i -	<u> </u>
Eiquid	Methane	1101	17	1 F	1 m	<u> </u>
C Salid	Methane Sulfonic Acid		1 F	L F	1 F	<u> </u>
	Methanesultonic Acid	MSA	R	L F	Ē	
C Gas	Methanesulfory/Chloride	MSC	2	Γ	Ē	
	Methanol	MEDH	_			2
	Methionine Ethyl Ester HD, I-					
Activity Description	Methopy Ethyl Ether, 2-		L L	Г		
RAW MATERIAL	Methoxy phenyl acetonitrile,4-		Г	Г	Г	Г
	Methowyacetophenone, p-		Г	Г	Г	Г
Quantity	Methowethanol, 2-		L L	L L	F	
Quantity Units	Methow/amine Hydrochloride		Г	Г	Г	
	performation to see to state a		1	-	-	
25 LITERS 💌	U.4					•

Figure 10. Chemical Activity Screen.

On this screen, the user can add or remove chemicals from the unit operation and set the quantity of the material selected. The Addition activity allows the user to select the following:

- Raw Material
- Adjustment (addition)
- Transfer To

The Removal activity is where the user documents what is removed in this batch step and the fate of the removed material. The removal selections are as follows:

- Adjustment (removal)
- Dissolved Solid
- Drums
- Hazardous Waste
- Off-Gas
- Product
- Reclaim
- Transfer From

Selecting the Control Devices tab (Figure 11) displays the control devices that may be attached to the vessel in this unit operation. The user can add as many control devices as required. Clicking on a control device (highlighted) in the top grid will display the control efficiency of the device and the after control emissions for each chemical in the unit operation in the grid on the bottom half of the screen.

		Controls				Controls
Vessel Step #	Control # Tag Number	Unit Type		Input Temperature ("C)	Exit Temperature [1	Top
R-300A 1	1 [COND-1	Condenser		15	5	Brevious
						Diext
						Botom
						Save
			_			Cancel
	New Control Device	Edit Control Device	Remove	Control Device		∆dd
		Control Efficiencies & Emissi	iona			Copy.
Chemical		Abberviation Use Det. EH.	Def. Eft. Efficiency		Lb/Operation	Block Repeat
Methanol	ME	OH Yes	44	.78 0.0270	0.0270	Delete
				0.0270	0.0270	Teleje
						Find
						Re-Order Ops
						Re-Celc Cempeign
						Herbau companye
						Select.Experiment
						VapoyBori Calc

Figure 11. Unit Operation Control Devices screen.

Selecting the Emissions tab (Figure 12) displays the pre- and post-controlled emission for each chemical in the unit operation in pounds per hour and for pounds per operation.

Chemical Name	Abbreviation	Step Vessel	Before Control Actual Lb/Hour	Alter Control Actual Lb/Hour	Before Control	After Control Lb/Operation	Controls
Nethanol	MEOH	1 R-300	0.0489	0.0270	0.0489	0.0270	Brevious
			0.0489	0.0270	0.0489	0.0270	Next
							Bottom
							Save
							Egit
							bbA
							Copy
							Block Repet
							Delete
							Find
							Re-Order Ops
							Re-Celc Campai
							Select Experime
							Vapor/Boil Calo
							Qose

Figure 12. Unit Operation Emissions screen.

The Emission Summary screen (Figure 13) shows a roll-up of the emissions by species for each vessel in the experiment and also displays the vessel's emission limits by species.



Figure 13. Unit Operation Emissions Summary Screen.

REPORTS

The reports in the Emission ProFiler system are used to provide compliance information for federal, state and internal reporting needs. The various reports in the EP system are listed in Figure 14. The reports in EP were developed using Business Objects' Crystal Reports.

Figure 14. Emission ProFiler Report Types.

🗱 Reports	
Report Type-	
 Activity Summary Chemical 	
C Calculation Documentation	
C Emission Statement Totals	
C Emissions by Stack	
C HAP Totals	
© NJDEP DEQ117 - Annual Report	
NJDEP DEQ-117E - Pre-Calculation	
NJDEP DEQ-117F - Post-Calculation	
SARA 313 Chemical Totals	
C Tracking of Production Days	<u>O</u> k
C VOC Totals	Close

Figures 15 and 16 shows an example of the New Jersey Post Experiment Review Form. This report displays the emissions from each vessel used in the experiment and compares the emissions by regulated species to the required emission limits. This report is required after every experiment is run to document the experiment compliance status.

Figure 15. New Jersey Post Experiment Review Form – Page 1.

DEQ-117F Page 1

PILOT PLANT IN-HOUSE POST EXPERIMENT REVIEW FORM

1.	Test Date:	1/1/1900	Experiment Identification #:	2006 TEST 1					
2.	Experiment I	f itle: 2006 TEST 1	Pre-Experiment Identification	1 #:					
3.	Emissions:		Recalculation of emissions (see page 2)						
			Emissions are adequately represented by the Pre-Experiment Review ran within the expected parameters of the emission calculations.	/Form.Experiment					
4.	4. Describe any upsets or equipment malfunctions which may have affected emissions:								
5. Continuous Emission Monitors used (if applicable):									
6.		Check here if per	mit limit was exceeded.						
	Any exceeda	nce of operating o	r emission requirements specified by the Department must be reporte	d to the Regional Office within one					

Any exceedance of operating or emission requirements specified by the Department must be reported to the Kegional Office within one working day by telephone and within three working days in writing after knowledge of the exceedance. However, any operation of the equip iment which may cause off-p roperty effects, including odors, shall be reported immediately by calling the HOT LINE 609-292-7172, in accordance with the Air Polution Control Act, 26:2C-19 (e).

7. Signature:

Figure 16. New Jersey Post Experiment Review Form – Page 2.

DEQ-117F Page 2

Experiment Identification #: 2006 TES T 1 Experiment Title: 2006 TES T 1 Date: Thursday January 25, 2007 at 10:25:41PM

Source Designation:

R-300A

	LBS/HR					
Category	Actual	Permit				
Subcategory	Maximum	Allow ab le				
со		4.000				
NOx		4.000				
S O2		4.000				
T SP		2.500				
PM2.5		N/A				
PM10		2.500				
HAP	0.466	N/A				
Total VOC	0.466	2.500				
TXS		0.000				
MeCE		2.500				
Greenhouse		N/A				

🗵 Batch has met NJDEP guidelines for summary emissions limits.

□ Batch has failed to meet NJDEP guidelines for summary emissions limits:

Figure 17 shows an example of one page of a Calculation Documentation report. This report is for an evacuation unit operation in the batch record, pages of this report detail the calculation methodologies and provides the specific EPA reference for the equations used.

Campaign #: 2006 TEST 1 Unit Type: Reactor Tag #: R-300A Process Condenser: None Continuous Sweep: No Sweep Rate: 5.0			0	Operation #: 4.00 Unit Operation: Evacuation Step #: 1 Equation Namie: Evacuation Equation Set: OAGPS 1994					
Step 11. Calculate the unc	ontrolled e	mission	n rate of each cons	tituent				OAQP5 1978	EQ. #2
	CE -	(760) (X) (VRS) (M	N)					
	SE =		(R) (T)						
Where,	X VRS MW T R	= = = =	mole fraction volume of tota molecular wei temperature (ideal gas law	al VOC v ght °K)	apor dise			iole °K	
Chemical Name Methanol	<u>Abbre</u> MEOI	<u>viation</u> H	<u>P (mm Hg)</u> 0.00	<u>보</u> 1.00	<u>VRS</u> 37.37	<u>MW</u> 32.00	T_(*K) 298.15	<u>SE (bAr)</u> 3.9028	

Figure 17. Example of the Calculation Documentation Report Detailing Unit Operation Calculations.

Product: 2006 TEST 1

Step 12. Calculate the uncontrolled emission rate per operation over multiple purges.

Department: 2006

SE (lb/hr) = SE (lb/hr) * Number of Purges

SUMMARY

Emission ProFiler is a valuable program that provides succinct environmental assessment of R&D API processes. This tool is invaluable in the lab to kilo/ pilot scale-up phase of development and is of necessity before tech transfer to a manufacturing facility is considered. Simplicity, flexibility and speed give Emission ProFiler an advantage over mass-marketed alternatives that tend to create bottlenecks. Based upon sound, pre-loaded equations (OAQPS¹, CTG² and MACT³), engineers can model R&D processes and gain immediate feedback regarding environmental compliance with NJDEP-issued Air Permits.

REFERENCES

1. Control of Volatile Organic Emission from Manufacture of Synthesized Pharmaceutical Products; U.S. Environmental Protection Agency; Research Triangle Park, 1978; EPA-450/2-78-029.

2. Control of Volatile Organic Compound Emissions from Batch Processes – Alternative Control Techniques Information Document; U.S. Environmental Protection Agency; Research Triangle Park, 1994; EPA-450/R-94-020.

3. National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production – Proposed Rule; Federal Register: April 10, 2000; 65 FR 19152.

KEY WORDS

Batch Emission Calculation, Emission Inventory, Environmental Data Management